

FDA CONSUMER

SEPTEMBER 1976

The Common Cold: Relief But No Cure





This Month

A speech or article that is long on fiery rhetoric but short on useful information is said to generate more heat than light. Mercury vapor lamps are a source of illumination that produces considerable light, but they also may emit ultraviolet radiation that can't be seen but can have unwanted effects on people who are exposed to it. Sunlamps, which give off light although that is not their main purpose, also produce unseen ultraviolet radiation that can be a cause for concern. FDA's responsibility is to assure that consumers are adequately protected from the radiation hazards of light sources. The problems, and what FDA is doing about them, are examined this month under the heading *Shedding Some Light on Light*.

Of subjects that have produced waterfalls of words but only trickles of useful information, treatment of the common cold has to be high on any list. Down through the years advice on cold cures has been almost as limitless as man's imagination. One remedy—the so-called two-hat cure—calls for the patient to drink enough whiskey to see double. Although there have been no documented cures from this treatment, it has been known to produce a hangover that makes the patient forget completely about the cold—at least temporarily.

Enlightenment of a more realistic nature on remedies for the common cold comes from an FDA advisory panel. The panel's primary task was to review the safety and effectiveness of the ingredients used in the thousands of cough, cold, and related products that can be obtained without a doctor's prescription. A summary of the panel's findings and recommendations begins on page 4.

In recent years, FDA and industry have taken a number of steps to respond to growing demands from consumers for more information about the food they buy. Among the newer shopping aids are nutrition labels, open dating, and unit pricing. But do consumers make use of these and other aids intended to make them better informed about what they're getting for their food dollar? In other words, *Are Americans Careful Food Shoppers?* which just happens to be the title of our article on an FDA survey that sought to answer that question.

This month's lineup of articles also includes *FDA Goes on a Monomer Hunt*, a report on how the Agency monitors food packaging materials, and *The Great Grain Rescue*, an account of the salvage efforts triggered by the biggest grain disaster in U.S. history.

Inside Front Cover Photo: *In a specially designed laboratory, an FDA technician maps the light distribution of a mercury vapor lamp to determine whether there are any hot spots—abnormal concentrations of light—in the illuminating field. For more on FDA's role in regulating devices that might emit harmful radiation along with light, turn to page 10.*

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FDA CONSUMER was previously known as **FDA PAPERS**.

Section 705 [375] of the Food, Drug, and Cosmetic Act:

(a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

Cover Design: Cameron Gerlach

Consumer Forum

Cyclamate Decision Criticized

The cyclamate article appearing in the June 1976, issue of FDA CONSUMER includes serious misrepresentations of the National Cancer Institute (NCI) Committee Review and ignores the fundamental evidence establishing the safety of cyclamate.

The NCI Committee stated that "the sole function given to, and assumed by, the Committee was to determine the carcinogenicity of cyclamate based on a review of the available information." Several times the Committee noted: "The present evidence does not establish the carcinogenicity of cyclamate." The NCI Committee specifically stated: "None of these studies, when considered alone or even collectively, satisfy the Committee's criteria for concluding that cyclamate is a carcinogen." The Committee said: "Cyclamate has pushed the technology of carcinogenicity testing to its limit."

Your article also stated: "FDA concluded that cyclamate in large amounts can affect growth and reproduction, as well as cause testicular atrophy and elevated blood pressure in test animals." This "conclusion" is difficult to reconcile with the findings of the principal study in this area, the scientific report of which emphasized: "The physical and clinical observations in the test groups fell substantially within normal limits and were not significantly different from the untreated controls." The study further stated that the substance tested "was not carcinogenic and thus not etiologically responsible for the bladder carcinomas in this strain of rats, which resulted in the banning of cyclamates by the Food and Drug Administration."

The FDA Commissioner's decision to continue the FDA ban on cyclamate works an undue hard-

ship on millions of American consumers, particularly those suffering from diabetes and chronic obesity. The same data on cyclamate has been reviewed by many top-flight sophisticated teams of scientists representing governments around the world. Switzerland, Finland, Canada, West Germany, and the World Health Organization all have concluded that the evidence does not show cyclamate to be a cancer-causing material, and today cyclamate is in use in numerous countries. The NCI panel came to the same conclusion, as did scientists in FDA's Bureau of Foods.

We believe it is essential that the Commissioner reconsider and reverse his position in view of the evidence.

Robert H. Kellen
President, Calorie Control Council
Atlanta, Georgia

The law requires FDA to have evidence of an additive's safety before it can approve the additive for use in food. If there are unresolved questions about an additive's safety FDA believes the public interest requires that they be answered before the additive is approved.

The National Cancer Institute Committee said it could reach "no conclusion" on cyclamate's potential for causing cancer in humans. Although it acknowledged that data from animal experiments do not prove the cancer-causing effects of cyclamate, the Committee went on to say: "Such data do suggest, however, that cyclamate may be potentially carcinogenic and, therefore, warrants further study."

In announcing his decision, Commissioner of Food and Drugs Alexander M. Schmidt, M.D., said that based on the scientific evidence available he could not "assure the American people that cyclamate is safe for use as a sugar substitute" and, therefore, could not allow it back on the market.

Quotes

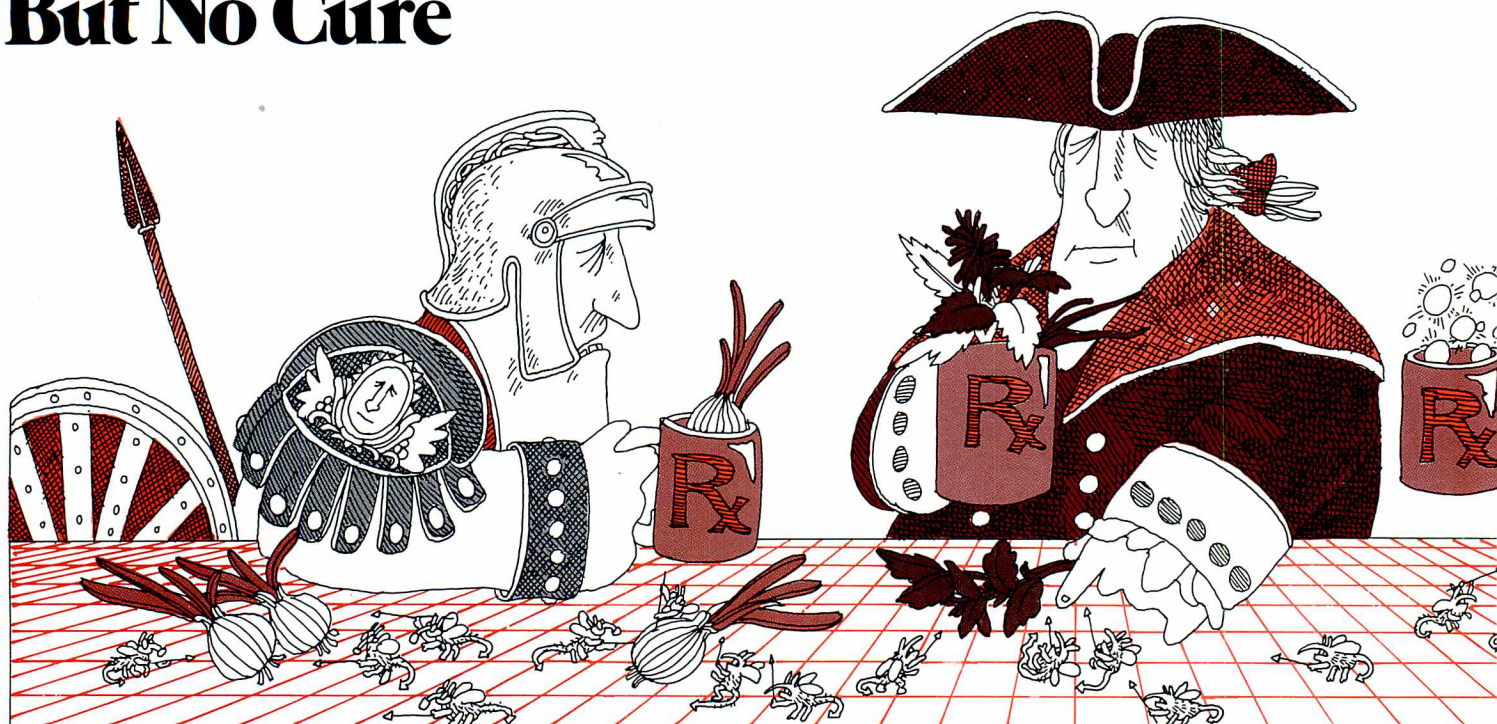
"Artificial conflicts between groups of people must not be allowed to replace the very real conflicts among the desires and needs of our society.

We want our equipment and plants to be clean and sanitary, but we also want to conserve water and energy. We want to dispose of our wastes without polluting our streams and lakes, but we don't want to contaminate our crops with heavy metals and industrial chemicals. We want our fields and pastures to be productive, but we don't want our foods contaminated with pesticides and hormonal or

other residues of questionable effect upon human beings. We want convenience in food preparation and consumption, but we also want balanced nutrition without having to become nutrition experts. Increasingly we want to 'eat out,' but we don't attach as much importance to the training of the kitchen help as we do to the figure of the waitress or the demeanor of the maitre d'. We assume that the Government will assure the safety of our foods and protect us against the unscrupulous and the ignorant, but we protest the cost of over-regulation, surveillance and red tape."

Howard R. Roberts, acting director, Bureau of Foods, Food and Drug Administration, at a meeting of the Can Manufacturers Institute.

The Common Cold: Relief But No Cure



After reviewing the ingredients that go into thousands of nonprescription drug products, an FDA advisory panel has concluded that a number of them will relieve cold symptoms but there is still no cure for one of mankind's most familiar maladies. The panel studied some 90 active ingredients that are used in cough, cold, and related products and gave its views on the safety and effectiveness of each one.

by Annabel Hecht

Had you lived in ancient Rome you might have sipped a broth made by soaking *Allium cepa*—an onion—in warm water to relieve the symptoms of the common cold. In Colonial America you might have relied on pennyroyal tea or an herbal concoction made from such unmedicinal sounding plants as sage, hyssop, yarrow, black cohosh, buckthorn, coltsfoot, goldenseal, cubeb berries, or bloodroot. In grandma's time, lemon and honey was a favorite recipe, or in extreme cases, a hot toddy laced with rum—the amount of same determined by the age of the drinker.

Today, if you don't have an old reliable remedy to fall back on, you might take one of literally thousands of drug preparations available without prescription. Some contain ingredients reminiscent of the folk medicine of the past; others are formulated with sophisticated chemical creations. Old or new, simple or sophisticated, many of these remedies will relieve some of the familiar cold symptoms, such as stopped up nose or hacking cough. But not a single one of these products—on which Americans spend an estimated \$700 million a year—will prevent, cure, or even shorten the course of the common cold.

So says a panel of non-Government experts called on by the Food and Drug Administration to study the safety, the effectiveness, and the accuracy of claims made on the labels of some 50,000 cold, cough, allergy, bronchodilator, and antiasthmatic drug products. The Panel is one of 17 set up by FDA to examine all nonprescription (over-the-counter) drugs marketed in the United States. The project, mandated by a 1962 Amendment to the Food, Drug, and Cosmetic Act which requires that all drugs be proven

effective as well as safe, will eventually lead to the establishment of definitive Federal standards on ingredients and labeling claims for all nonprescription drugs.

The Panel indicated that proper use of nonprescription drugs can be effective in relieving cough, sinus congestion, runny nose, and some of the other symptoms associated with colds, allergies, or asthma. But it made clear that although these products may relieve certain symptoms they will not cure any of these conditions.

One aspect of this class of drugs that concerned the Panel was the relative scarcity of single ingredient products on the market. This is particularly true of cough and cold remedies. The common cold is a self-limiting respiratory infection which lasts from one to two weeks. It usually starts with a sore throat, sneezing, and runny nose. After a few days, the nose becomes stopped up and the eyes become watery. This is followed by lethargy, aches and pains, and sometimes a slight fever. Cough may occur in the later stages. Often these symptoms do not occur at the same time. Nevertheless, almost 90 percent of cough and cold products



now available contain a combination of ingredients intended to relieve a number of different symptoms. Only 46 of the cough-cold products examined by the Panel consisted of a single active ingredient.

The Panel said it is "irrational" to take a combination product unless each of the ingredients is necessary to relieve the patient's particular symptoms. Moreover, because of variations in individual reactions to drugs, fixed combinations may not be suitable for some people. Consumers need more choice in selecting the appropriate treatment for their symptoms, the Panel said, and recommended that all products to relieve cough and cold symptoms be available in both combination and single ingredient form.

Another area of concern to the Panel was labeling of cough and cold remedies. It said labeling for these products "tends to be overly complicated, vague, unsupported by scientific evidence, and in some cases is misleading." The Panel called for an end to claims that one product is superior to, stronger than, or contains more active ingredients than another, or is specially formulated. Under its recom-

mendations such words as "cold medicine," "cold formula," or "for the relief of colds" would be banned from drug labels. Such claims suggest the product will cure a cold when the best it can do is relieve specific symptoms, the Panel said.

One of the most distressing symptoms of the common cold is sore throat and many nonprescription drug products claim to provide relief for this condition. The Panel noted, however, that sore throat can be due to serious infection which should not be treated by self-medication. It recommended that labels on cough, cold, and related nonprescription drugs limit their claimed effectiveness to "minor throat irritation" and should advise consumers to seek medical help for serious throat problems.

Timed-release formulations also came under the scrutiny of the Panel, which found advantages and disadvantages in this type of medication. Obviously it is easier to take one pill instead of two or three, especially at night, but variations in the rate at which ingredients dissolve, differences in individual patient reactions, and even technical flaws in the manufacturing process could mean that the medicine could be absorbed erratically or possibly all at one time. Therefore, the Panel recommended that a four-year period be allowed for industry, in cooperation with FDA, to develop suitable tests for the standardization of all nonprescription timed-release cough-cold products and that timed-release claims not be permitted in labeling unless such claims have been documented.

Children represent a substantial portion of the consumers of cough and cold remedies, yet the Panel found that information on how these drugs affect them is "negligible or non-existent." Lacking definitive data, the Panel sought the advice of a group of experts on pediatric drug therapy in developing the following recommendations: the dose for children 6 through 11 should be half the adult dose, and for youngsters 2 through 5 it should be one quarter of the adult dose. Asthma and cough preparations should not be taken by children 2 through 5 in any amount except on the advice of a physician. Any product with an alcoholic content of more than 10 percent is not for children under 6, the Panel noted.

As for infants up to 2 years of age,

the Panel said dosage should be determined by a physician and the labels on nonprescription drug products should make this clear. Labels should never carry a recommended dose for these youngsters unless the product has been demonstrated to be safe for them, the Panel said.

In reviewing all cough, cold, allergy, bronchodilator, and antiasthmatic nonprescription drug products the Panel studied some 90 active ingredients. These ingredients were divided into six groups (plus a miscellaneous classification):

- Antitussives, which are cough suppressants.
- Expectorants, which help bring up mucus in the bronchial airways so it can be spit out.
- Bronchodilators, which enlarge the bronchial passages to make it easier for people with asthma to breathe.
- Anticholinergics, which dry up watery secretions in the nose and eyes.
- Nasal decongestants, which open up the nasal passages.
- Antihistamines, a class of drugs used to relieve sneezing and watery and itchy eyes, usually associated with hay fever and other allergies.

Each ingredient reviewed was placed in one of three categories:

Category I—Generally recognized as safe and effective and not mislabeled.

Category II—Not generally recognized as safe and effective or mislabeled. Such ingredients and labeling claims will be removed from products within six months after FDA issues its final regulations on cough, cold, and related nonprescription drug products.

Category III—Available data insufficient to permit final classification at this time. The Panel recommended that when FDA issues its final regulations ingredients which are placed in this category be permitted to remain on the market for a stipulated length of time if the manufacturer immediately begins tests to satisfy the questions raised by the Panel.

Lucky is the cold victim who has only an annoying tickle in his throat or a stuffed up nose. The Panel found 7 ingredients both safe and effective as cough suppressants and 14 safe and effective as nasal decongestants. It recommended that one of the cough suppressants and four of the nasal decongestants which are now available only in dosage levels that require a prescription be made available in ef-

fective dosages that could be sold without a prescription.

Not so fortunate is the person whose cough is "nonproductive" or produces only small amounts of thick phlegm. Not one ingredient was found by the Panel to be both safe and effective as an expectorant. Similarly, the Panel found no ingredient both safe and effective as an anticholinergic to relieve watery secretions of nose and eyes.

Fifteen of the ingredients it studied are not generally recognized as safe and effective for cough and cold symptoms and should be taken off the market, the Panel reported. One of these is chloroform, which FDA already has banned on the basis of evidence that high doses of it can cause cancer in test animals.

A wide array of ingredients—52 all told—were considered by the Panel to be safe enough, but further proof of their effectiveness in relieving coughs and stuffy or runny noses is needed. Scattered throughout the list are names reminiscent of patent medicines and home remedies of the past: cod liver oil, slippery elm, cedar leaf oil, horehound, camphor, menthol, and oil from the koala bear's favorite food, eucalyptus leaves. The Panel recommended that these familiar remedies—as well as the rest of the 52 whose effectiveness it questioned—be permitted to stay on the market for from three to five years if their manufacturers undertake further tests to prove (or disprove) that grandma knew all along what was good for the sniffles.

As for the labeling of cough and cold remedies, the Panel recommended that cough suppressants be permitted to claim that they temporarily relieve coughs due to minor throat irritation, help to quiet the cough reflex, or help you to cough less. But the labels should warn that a cough may be a sign of a serious condition and that a physician should be consulted if it lasts more than one week. The Panel also recommended a warning that cough suppressants should not be used for persistent or chronic coughs such as occur with smoking, asthma, and emphysema. In such cases, coughing is essential to rid the bronchial airways of mucus and other secretions. Cough suppressant labels should not refer to lung or chest conditions, the Panel said, nor should they claim the product works by soothing the bronchial passages.



The Panel said expectorant labels should be permitted to claim that the product helps loosen phlegm or rid passageways of bothersome mucus, but it called for a warning against taking expectorants for persistent chronic cough associated with smoking, asthma, or emphysema, or if there are excessive secretions, except under the advice of a physician.

Labels on anticholinergics could promise temporary relief of watery nasal discharge, or runny nose or watering of the eyes, but such statements as "clears nasal passages" or "opens airways" would not be permitted under the Panel's recommendations. Consumers should be warned not to take anticholinergics if they have asthma, glaucoma, or difficulty in urinating, the Panel said.

Topical nasal decongestants, those applied directly in the nose, present a unique problem. These drugs help clear up stuffy noses by constricting enlarged blood vessels in the nasal passage. But if they are used for too long a time or too frequently they can have the opposite effect and actually enlarge, rather than constrict, the blood vessels. Therefore, the Panel recommended

that labeling for topical nasal decongestants warn users not to exceed the recommended dosage and not to use the product for more than three days. If symptoms persist, a physician should be consulted.

Oral nasal decongestant labels should warn against use by persons suffering from high blood pressure, heart disease, diabetes, or thyroid disease unless under a physician's supervision, the Panel said. And products that are inhaled should carry the caution statement: "Not for use by mouth."

Approximately six million people in this country suffer from asthma, a disease marked by wheezing, coughing, and shortness of breath. Many of these people use nonprescription drugs called bronchodilators to help them breathe more easily, and the Panel found 12 ingredients safe and effective for this purpose. Five of them are now available only by prescription, and the Panel proposed that they be changed to over-the-counter status.

Because of variations in the way the body breaks down the two types of drugs most often used as bronchodilators, the Panel said that single ingredient preparations are more effective

Ingredients: What The Panel Said

Cough and Cold Remedies

The Panel found that the following ingredients are generally recognized as safe and effective and are not mislabeled.

Antitussives (cough suppressants)

Codeine
Codeine alkaloid
Codeine phosphate
Codeine sulfate
Dextromethorphan
Dextromethorphan hydrobromide
Diphenhydramine hydrochloride

Expectorants

none

Anticholinergics

none

Nasal Decongestants

Ephedrine
Ephedrine hydrochloride
Ephedrine sulfate
Racephedrine hydrochloride
Naphazoline hydrochloride (topical)
Oxymetazoline hydrochloride (topical)
Phenylephrine hydrochloride (oral/topical)
Phenylpropanolamine bitartrate (oral)
Phenylpropanolamine hydrochloride (oral)
Phenylpropanolamine maleate (oral)
Propylhexedrine (inhalant)
Pseudoephedrine hydrochloride (oral)
Pseudoephedrine sulfate (oral)
Xylometazoline hydrochloride (topical)

The Panel found that the following ingredients are not generally recognized as safe and effective or are mislabeled.

Antitussives

Hydrocodone bitartrate
Oil of turpentine (oral)

Expectorants

Antimony potassium tartrate
Calcium iodide anhydrous
Chloroform
Hydriodic acid syrup
Iodized lime
Ipecac fluidextract
Potassium iodide
Squill
Squill extract
Oil of Turpentine (oral)

Anticholinergics

Atropa belladonna (inhalant)
Datura stramonium (inhalant)

Nasal Decongestants

Mustard oil (topical/inhalant)
Oil of turpentine (oral)

The Panel found that there are insufficient data to classify the following ingredients. It recommended that these ingredients be permitted to remain on the market from three to five years if their manufacturers immediately begin tests to answer the questions raised by the Panel.

Antitussives

Beechwood creosote
Camphor (topical/inhalant)
Caramiphen edisylate
Carbetapentane citrate
Cod liver oil
Elm bark
Ethylmorphine hydrochloride
Eucalyptol/eucalyptus oil (topical/inhalant)
Horehound (horehound fluidextract)
Menthol/peppermint oil (topical/inhalant)
Noscapine (noscapine hydrochloride)
Oil of turpentine (topical/inhalant)
Thymol

Nasal Decongestants

Beechwood creosote
Bornyl acetate (topical)
Camphor (topical/inhalant)
Cedar leaf oil (topical)
1-Desoxyephedrine (inhalant)
Ephedrine (oral)
Ephedrine hydrochloride (oral)
Ephedrine sulfate (oral)
Eucalyptol/eucalyptus oil (topical/inhalant)
Menthol/peppermint oil (topical/inhalant)
Oil of turpentine (topical/inhalant)
Phenylpropanolamine hydrochloride (topical)
Racephedrine hydrochloride (oral)
Thenylidamine hydrochloride (topical)
Thymol (inhalant)

Anticholinergics

Atropine sulfate (oral)
Atropine (d, dl hyoscyamine) (oral)
Scopolamine (l-hyoscine) (oral)

Expectorants

Ammonium chloride
Beechwood creosote
Camphor (topical/inhalant)
Compound tincture of benzoin
(inhalant)

Compound white pine syrup
Eucalyptol/eucalyptus oil
(topical/inhalant)
Extract white pine compound
Glyceryl guaiacolate
Ipecac syrup
Menthol/peppermint oil
(topical/inhalant)
Oil of turpentine (topical/inhalant)
Pine tar
Potassium guaiacol sulfonate
Sodium citrate

Syrup of pine tar
Terpin hydrate
Terpin hydrate elixir
Tincture of benzoin (inhalant)
Tolu
Tolu balsam
Tolu balsam tincture
White pine

Allergy Remedies (Antihistamines)

The Panel found that the following ingredients are generally recognized as safe and effective and are not mislabeled.

Brompheniramine maleate
Chlorpheniramine maleate
Diphenhydramine hydrochloride
Doxylamine succinate
Methapyrilene fumarate
Methapyrilene hydrochloride
Phenindamine tartrate
Pheniramine maleate
Promethazine hydrochloride
Pyrilamine maleate
Thonzylamine hydrochloride

The Panel found that there are insufficient data to classify the following ingredients. It recommended that they be permitted to remain on the market for three years if their manufacturers immediately begin tests to answer the questions raised by the Panel.

Phenyltoloxamine citrate
Thenylidamine hydrochloride (oral)

Asthma Remedies (bronchodilators)

The Panel found that the following ingredients are generally recognized as safe and effective and are not mislabeled.

Ephedrine
Ephedrine hydrochloride
Ephedrine sulfate
Racephedrine hydrochloride
Epinephrine
Epinephrine bitartrate
Epinephrine hydrochloride (racemic)
Methoxyphenamine hydrochloride
Aminophylline
Theophylline anhydrous
Theophylline calcium salicylate
Theophylline sodium glycinate

The Panel found that the following ingredients are not generally recognized as safe and effective or are mislabeled.

Atropa belladonna (inhalant)
Datura stramonium (inhalant)
Pseudoephedrine hydrochloride
Pseudoephedrine sulfate

The Panel found that there are insufficient data to classify the following ingredient. It recommended that this ingredient be permitted to remain on the market for three years if the manufacturer immediately begins tests to answer the questions raised by the Panel.

Euphorbia pilulifera



and safer to use than combination products. It also cautioned that bronchodilators not be used unless a diagnosis of asthma has been made and then only under the supervision of a physician.

Because bronchodilators can have adverse effects on the circulatory and central nervous systems, they should carry labels warning against use by persons suffering from high blood pressure, heart disease, thyroid disease, diabetes, or enlargement of the prostate gland, the Panel said. Labeling also should warn the patient to seek help immediately if symptoms are not relieved in one hour—or in 20 minutes in the case of epinephrine taken by an inhaler. Bronchodilator labels should be permitted to claim that the product is for temporary relief or symptomatic control of bronchial asthma only, the Panel recommended, and there should be no suggestion that it will relieve hay fever or have any effect on the nasal passages.

The relief of hay fever should be left to the antihistamines, the Panel indicated. It found 11 ingredients from this class of drugs safe and effective for relieving the symptoms of allergic

rhinitis, or hay fever. Four of these are now available by prescription only, but the Panel recommended that they be approved for over-the-counter sale. Two antihistamines now used in hay fever products require further testing to demonstrate their effectiveness, the Panel said.

Although the antihistamines that are rated safe and effective have a low potential for side effects and toxicity they may cause drowsiness, the Panel pointed out, and it said this fact should be made known on the label. The label also should include a warning against use by people who have asthma, glaucoma, or enlargement of the prostate gland unless under the supervision of a physician.

Acceptable label claims for antihistamines should be that they are for the temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy and watery eyes as may occur in hay fever, but not for the relief of nasal symptoms, such as stopped up nose, nasal stuffiness, or clogged up nose, the Panel said.

Although antihistamines are widely used in the treatment of common cold symptoms, the Panel said there is

“little valid evidence” that they are effective for this purpose. Claims that antihistamines are effective for cold symptoms have not been substantiated by appropriate research, the Panel said, but it suggested ways these drugs could be tested for the common cold.

The Panel considered a number of ingredients which are often found in nonprescription cough-cold preparations, but which did not fall within the six main categories under review. These included antihistamines added to some cough-cold products as a sedative or sleep-aid. The Panel questioned the validity of adding an antihistamine to a cough or cold preparation for purposes of sedation and recommended that such combinations be taken off the market. But it said combinations that include an antihistamine “for restful sleep” should be allowed to stay on the market provided testing is undertaken by the manufacturer to establish an effective dose.

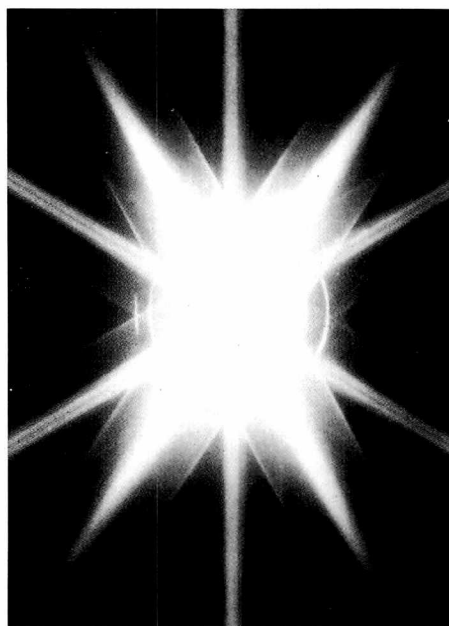
The Panel also called for additional testing to prove the effectiveness of caffeine, which is added to some cough-cold products to counteract drowsiness caused by other ingredients, and phenobarbital, which is added to offset central nervous system stimulants.

Label claims that vitamins, when used either alone or in combination with other products, are effective as cold preventives or cures should not be permitted, the Panel said. But the Panel added that manufacturers should be allowed to use vitamin C in cold products for three years if they want to do so in an effort to demonstrate its effectiveness, on the condition that no claims are made about the vitamin C.

The Panel’s report, the culmination of three years of study of this vast array of ingredients, is advisory in nature. It was published by FDA in the FEDERAL REGISTER to allow for comments from industry and consumers. After reviewing the report and the comments on it, FDA will issue final standards for acceptable ingredients and labeling claims for cough, cold, and related over-the-counter drug products. As a result, many products may have to be reformulated and labeling and advertising claims may have to be changed, a process which may take place even before the final standards are issued.

Annabel Hecht is a staff writer with FDA’s Office of Public Affairs.

Shedding Some Light On Light



Earth's atmosphere protects us from the sun's intense ultraviolet rays, but when we go indoors we could be exposed to this same ultraviolet radiation from manmade electric devices. It's FDA's job to see that sunlamps, mercury vapor lamps and other equipment producing ultraviolet radiation are safe.

by Annabel Hecht

You can't see it, but a bee can. You can't touch it, but it can "touch" you, often in a most painful way.

"It" is ultraviolet radiation, a natural phenomenon that is often erroneously called ultraviolet "light." This confusion is understandable since ultraviolet radiation is associated with some sources of visible light. So-called black light, for example, is really long-wave ultraviolet radiation.

Radiation is energy moving through space as waves. Ultraviolet radiation is that part of the sun's electromagnetic spectrum that lies between visible light and x rays. A portion of the longer ultraviolet waves are the ones that give you a suntan—or a burn if you stay on the beach too long. Shorter waves would give you a severe burn if the ozone and other components in the atmosphere didn't prevent them from reaching the earth's surface.

Although nature shields us from

some of the sun's ultraviolet radiation, we can still be exposed to these dangerous rays because they are produced by certain artificial light sources. And because the Food and Drug Administration is responsible for protecting the public from electronic products, it is very concerned about "light."

Sunlamps are one such concern. Every year, an estimated 10,000 people burn themselves severely enough under sunlamps to require emergency hospital treatment. How many stay at home and suffer in silence is unknown. Young women—those of high school and college age—are most likely to overexpose themselves under sunlamps. Face and eyes are the areas most likely to be burned.

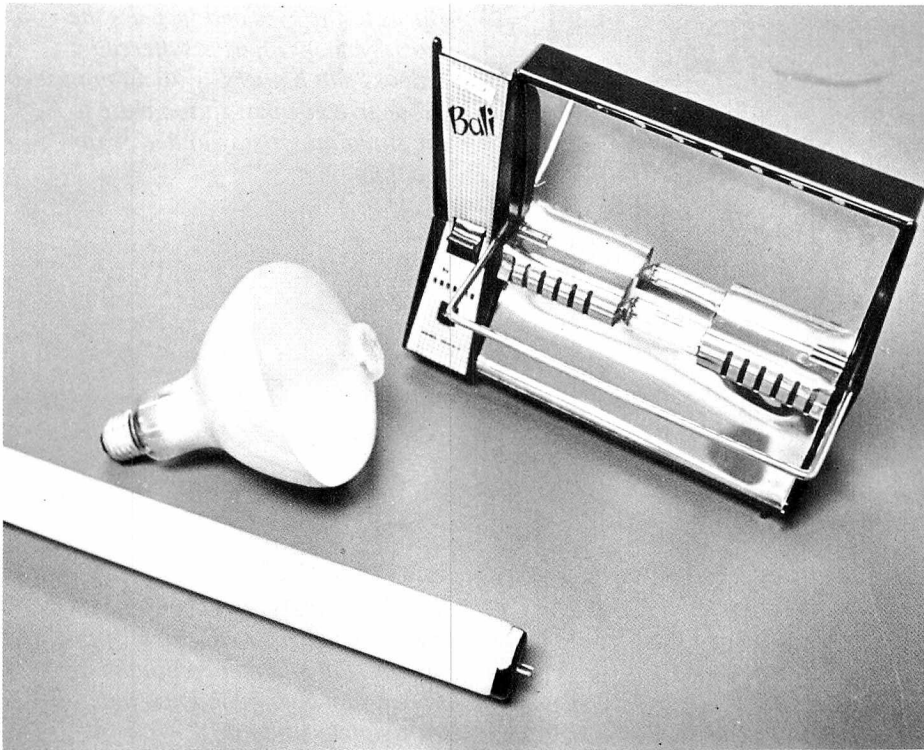
Many of the injuries from sunlamps occur because users ignore or forget the directions for safe operation of their lamp. They sit too close to the lamp or stay under too long, and scorn the use of goggles or sunglasses because they don't want to have white rings around their eyes. The result is not the bronzed skin they envisioned, but all too often a severe and painful burn. What they don't realize is that one minute under some sunlamps is equal to one hour under the sun.

Past FDA studies of sunlamps involved in injuries have shown that most lamps, especially those for home use, were sold without control devices

or timers. Only 10 percent of the lamps studied came with protective goggles. Instructions for proper use of the lamp were available in the majority of cases, but usually were in the form of printed material which could be lost or mislaid. Occasionally these instructions were given orally by a salesperson. Information on exposure time and the distance the user should be from the lamp were not included in some instructional material. In only a few instances was any safety warning affixed permanently on the lamp.

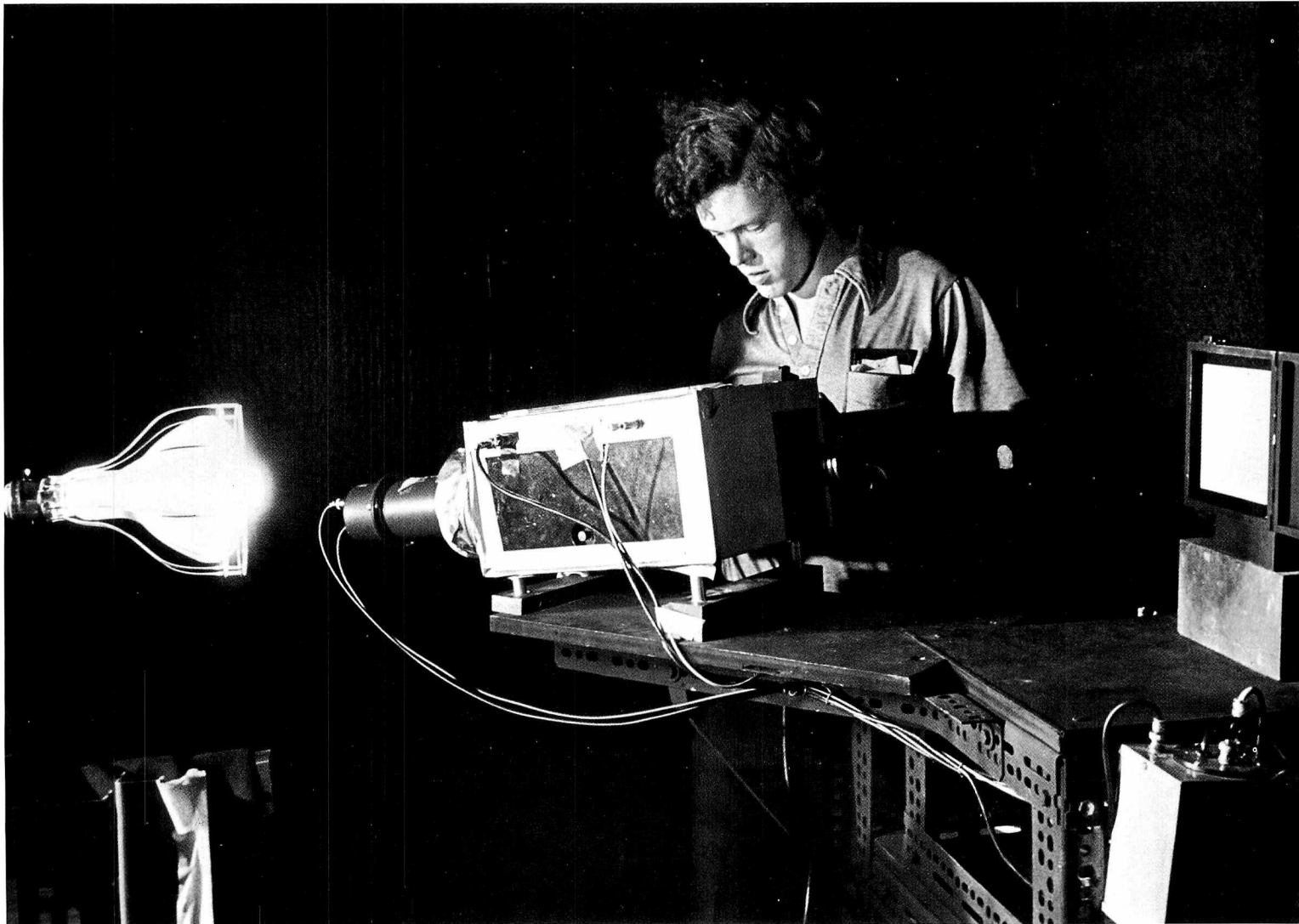
Because sunlamps do have a potential for harm, FDA, in early 1975, added them to the list of electronic products for which manufacturers are required to submit reports on design and emission characteristics. In addition, a performance standard including labeling requirements is being developed for sunlamp products. The proposed standard requires a timer to shut off the lamp at a preset time, a backup system to turn the lamp off if the timer fails, and a manual cutoff switch. Enough protective goggles for the maximum number of persons who could use the lamp at the same time also would be required. The proposed standard calls for modifications in the lamp base so that it cannot be used in an ordinary socket.

Warnings on the dangers of overexposure, use of protective eyewear,



Sunlamps come in a variety of shapes and sizes. Those that can be used in ordinary household sockets pose a number of problems since they have no timers, and the warning labels and instructions for use that come with them can be lost or mislaid.

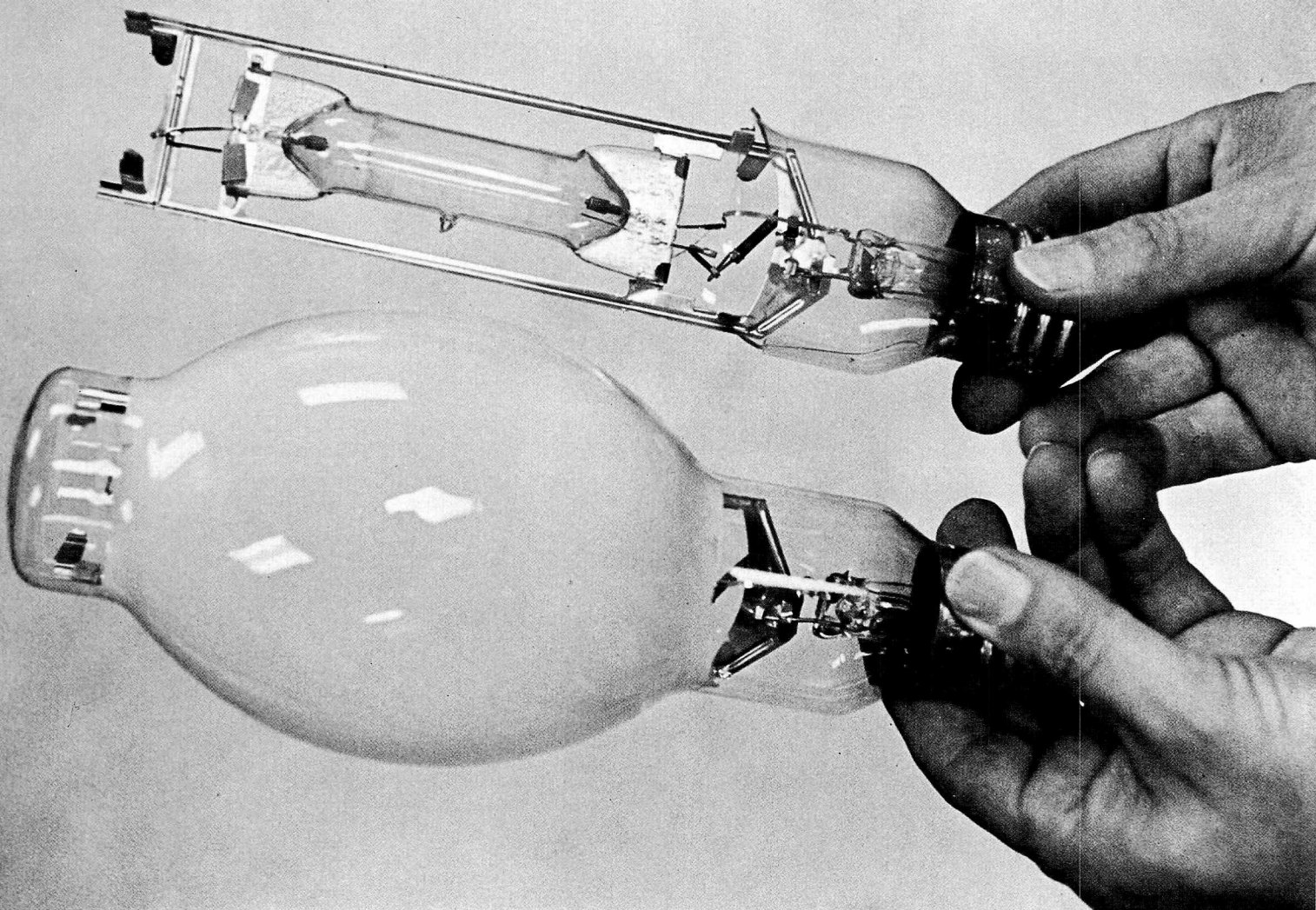
Bill Hensch, of FDA's Bureau of Radiological Health, checks the "spectral output" of a sunlamp to determine how much ultraviolet light is being emitted.





Burns to the eyes and face are the most frequent injuries suffered by indoor "sun bathers" who do not use protective goggles, sit too close to the sunlamp, or stay under its rays too long.

The intact mercury vapor lamp has a coated glass envelope. If this breaks, the unit can continue to operate, giving off dangerous ultraviolet radiation.



minimum safe distance between the lamp and user, and recommended exposure times would have to be included on a label to be prominently and permanently affixed to the sunlamp. Any printed instructional material supplied with the lamp also would have to include this information as well as a list of known adverse biological effects of ultraviolet exposure.

Another type of lamp under study by FDA because of problems with possible ultraviolet injury is the mercury vapor lamp, widely used to light streets, gymnasiums, sports arenas, banks, and stores. Highly efficient and exceptionally long-lived, mercury vapor lamps are two to three times more efficient than ordinary lamps and may last 6 to 7 years. An estimated 25 million of these lamps are in use today.

What makes the mercury vapor lamp work is an electrical current passing through a mercury-argon vapor contained in a quartz tube. To filter out shortwave radiation and protect the inner metal parts from oxidation, the lamp is surrounded by a hard borosilicate glass envelope. But if this protective envelope is broken most lamps will continue to operate, emitting unfiltered ultraviolet radiation.

FDA became aware of this potential health hazard in December 1974 when eight adults, who had been playing volleyball after school hours in a Maryland junior high school gym, suffered

unusual eye and facial injuries. The medical diagnosis: burns from exposure to ultraviolet radiation. One of the mercury vapor lamps in the gym had been broken earlier but was still burning when the men came to play. FDA experts examined similar damaged lamps and found they were emitting shortwave ultraviolet radiation.

FDA immediately alerted State health officials, other Federal agencies, and lamp manufacturers to this hazard and asked for information on similar injuries. As a result, at least eight more incidents involving more than 50 persons came to light. One report told of burns to the eyes and exposed skin of 10 spectators at a tournament in a high school gymnasium. Another involved injuries to players, referees, and coaches during a minor league hockey game in Canada. A broken lamp at an agricultural show in the northwest resulted in eye damage to a girl and to livestock.

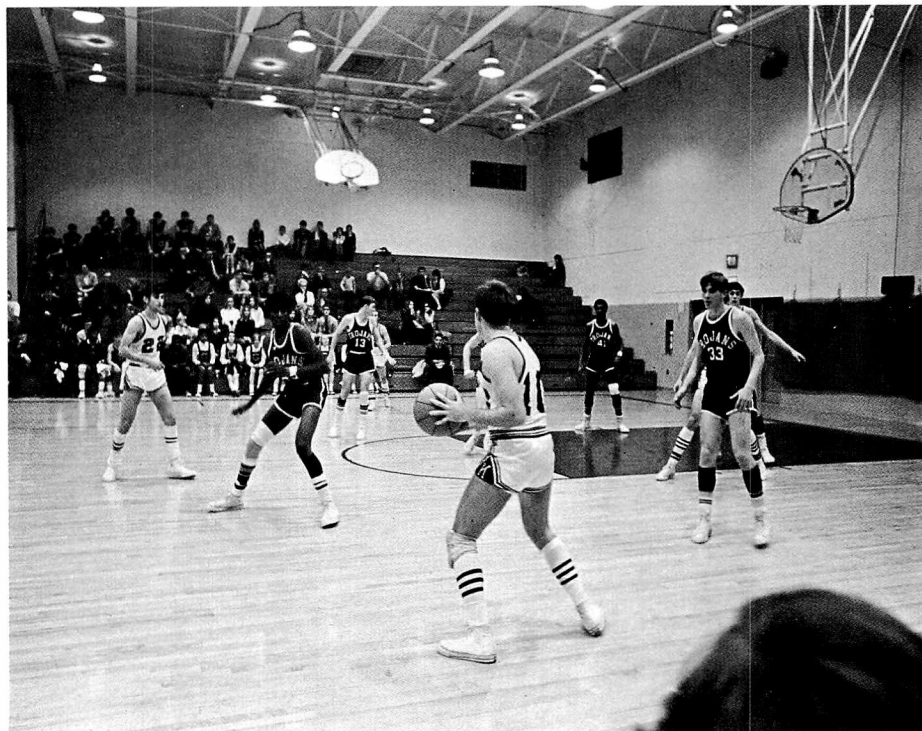
To reduce the risk of such accidents in the future, FDA is working with a special committee of the American National Standards Institute to develop voluntary standards for mercury vapor lamps which will probably require a self-extinguishing device that will put out the lamp within two minutes after the outer envelope is broken. Although it may be some months before work is completed on the standard, one such lamp is already on the market and

others are being developed.

In the meantime, FDA is continuing to monitor mercury vapor lamps since it is possible that some might emit potentially harmful radiation even with the protective outer envelope intact. FDA also has been looking into the potential hazards of tungsten halogen lamps, which have a variety of uses including lighting television studio sets, after learning of an incident in which 20 people suffered skin and eye burns during video-taping of a TV performance.

Not all mercury vapor lamps are used for general illumination. One that is not is a dental device called the Nuva-Lite Activator Light. Consisting of a small mercury vapor lamp in a "pistol grip" housing, the device delivers longwave ultraviolet radiation to harden plastic applied to the teeth in a restorative process. Unfortunately, the Nuva-Lite was doing much more than that. When a dentist reported that his eyes became sore and bloodshot after using the device, FDA checked and found that excessive radiation was leaking from the applicator—a potential danger to the patient—and unfiltered radiation was in most cases being emitted from the louvers on both sides of the lamp housing, frequently exposing the dentist to shortwave ultraviolet radiation. This was not an isolated case; many other injuries have been reported. The manufacturer

Burns caused by a mercury vapor lamp in a gymnasium provided the first evidence that these devices pose a potential radiation hazard. Mercury vapor lamps are widely used in gyms, and FDA has learned of instances in which fans and players have suffered radiation burns because the protective shield on one of the lamps broke, but the light continued to operate.



agreed to make appropriate modifications of all the devices in use and in stock.

FDA also is concerned about radiation emitted by lamps when they are used in a medical procedure called phototherapy. One such procedure is being tested in a treatment for psoriasis, a skin disease that does indeed cause heartache as well as physical suffering in severe cases. The treatment consists of a drug, 8-methoxypsoralen, taken orally, followed by whole-body exposure to a bank of fluorescent lamps which emit mostly longwave ultraviolet radiation and some visible light.

Already used with encouraging results in Boston and Vienna, Austria, the treatment is being tested on some 1,000 psoriasis patients in 16 hospitals throughout the United States to establish its safety and effectiveness. Since both a drug and the lamps are involved, two of FDA's bureaus—Drugs and Radiological Health—are cooperating in the evaluation of the treatment to determine whether it should be approved for general use.

The job of the Bureau of Radiological Health is to check the lamps for any unnecessary and dangerous shortwave and longwave radiation emissions, both in the laboratory and during actual use. The Bureau will also determine whether control features and use and maintenance procedures are adequate to assure radiation safety. Special protective

goggles worn by the patient during the treatment are being tested both by FDA and by the U.S. Air Force School of Aerospace Medicine. The Air Force testing is being conducted for FDA.

Visible light also is being used in the treatment and prevention of a condition that affects an estimated 35,000 newborn infants each year—hyperbilirubinemia—more commonly called jaundice of the newborn. The condition is caused by an increase of bilirubin, a breakdown product of red blood cells. If the bilirubin levels get too high, the infant may suffer neurological damage.

Since 1947, the standard treatment for this condition has been a complete exchange transfusion of the baby's blood. In 1958, a British physician found the jaundiced infants improved markedly after exposure to a blue fluorescent lamp as well as to sunlight. This treatment has been widely used in recent years although many questions regarding the effects of such exposure remain to be answered. FDA already has alerted physicians and hospitals to the risk of the infant developing erythema, or redness of the skin during treatment, and has recommended that lamps be shielded and the infant's eyes be protected, a measure also recommended by the National Academy of Sciences. FDA is cooperating with several branches of the National Institutes of Health in studies of the use of phototherapy to treat infant jaundice.

FDA fills yet another role in protecting the public from the radiation hazards of light sources. As advisor to the General Services Administration (GSA), the purchasing agency for the Federal Government, FDA passes on electronic products GSA is considering stocking in its supply stores. Recently, FDA turned thumbs down on a one million candle power hand held flashlight because of a possible ultraviolet radiation hazard.

There is still much to be learned about light and its effects on the human system. To help identify priorities for research, FDA is planning to establish an advisory committee which will include among its members researchers in the field of biological effects of light. In the meantime, FDA has stepped up its own studies in this area and is keeping tabs on all radiation-caused injuries serious enough for medical treatment through its Radiation Incidents Registry, operating in 120 hospitals throughout the country. Arc welding already has been identified as a major cause of ultraviolet injury because welders and the "sidewalk superintendents" who are watching them work often fail to protect their eyes from the glare of the intensely hot arc which is a source of ultraviolet radiation.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.

Are Americans Careful Food Shoppers?

Do most food shoppers make a list, read ads for specials, check ingredients? How much use is made of open dating, unit pricing, nutrition labels? FDA asked a sample of consumers about the aids they use to help them fill their shopping carts wisely.

by Joseph R. Pearce

What are some of the aids American shoppers use to make informed food purchases? Do most food shoppers make a list of items to be bought before going to the market? Do they read ads for specials? Do they check the list of ingredients on food packages, use open dating, unit pricing, and nutrition labels? In short, are Americans careful food shoppers in these respects?

To answer these and other questions, FDA contracted with Response Analysis Corporation to conduct nationwide surveys of American food shoppers in 1973 and 1975.

The 1975 findings—based on interviews with 1,664 shoppers—showed that the shopping aid used by the largest number of consumers was open dating, which tells the customer the date by which the product should be sold. About 75 percent of shoppers said they looked for open dating the last time they did the main food shopping, an 18 percent increase over 1973. Over the two-year period, open dating replaced reading ads for specials as the shopping aid used by the largest percentage of consumers.

Sixty-eight percent of the shoppers interviewed in 1975 said they read ads for specials, an eight percent increase over 1973. Only about 40 percent of the shoppers in both years said they looked for unit pricing the last time they were in the store. Although most shoppers keep a close eye out for specials, a majority have yet to use unit pricing. Unit pricing is a system used by some stores to help consumers compare prices of different sized packages of the same type of product. Shelf tags state the cost of an item per ounce or pound, thus making it easier for a



Table 1: Careful Shopper Score

	Low	Medium	High
All Food Shoppers	22%	50%	28%
Sex			
Female	20	50	30
Male	32	48	20
Education			
Less than High School	45	44	11
High School	20	51	30
College	14	52	34
Age			
18 - 34	20	50	31
35 - 49	19	52	29
50 - over	26	48	26
Race			
Non-black	20	51	29
Black	35	42	23
Socioeconomic Status			
Low	34	46	19
Medium	16	53	31
High	14	50	36
Nutrition Knowledge			
Low	32	48	20
Medium	21	49	30
High	12	53	35

NOTE: Total percentages may not add to 100 due to rounding of decimals.





Table 2: Use of Nutrition Labeling

	Have Used	Have not Used	Not Sure/ No Answer
All Food Shoppers	33%	66%	1%
Sex			
Female	35	65	0
Male	22	76	2
Education			
Less than High School	17	83	0
High School	32	67	1
College	42	57	1
Age			
18 - 34	43	57	0
35 - 49	32	67	1
50 - over	25	74	1
Socioeconomic Status			
Low	24	75	1
Medium	35	64	1
High	41	58	1
Nutrition Knowledge			
Low	22	77	1
Medium	33	66	1
High	45	54	1

consumer to make a price comparison between a 16-ounce can of peas and a 24-ounce can of peas.

The proportion of shoppers who made a shopping list before leaving for the market—approximately 62 percent—remained about the same in 1975 as it was in 1973.

Only forty-six percent of those interviewed in 1975 indicated that they checked the list of ingredients on cans or packaged foods (up a few percentage points from 1973) and only 33 percent said they have used nutrition labels for the purpose of making choices between different foods.

Based on the 1975 research, a "careful shopper" score was constructed by giving each shopper interviewed a point for every one of the shopping aids used: making a shopping list, reading for specials, checking lists of ingredients, using unit pricing, looking for open dates, and using nutrition labels. A score of zero to two points was considered "low," three or four points—"medium," five or six—"high." On the basis of this scoring system, 22 percent of the shoppers interviewed scored low, 50 percent

medium, and 28 percent high. (See Table 1.)

The survey showed that women tend to be more careful shoppers than men. Three out of ten men scored low on careful shopping compared to two out of ten women, while two out of ten men and three out of ten women scored high.

There is a slight tendency for younger shoppers to be "more careful" than older shoppers. Shoppers with more education, higher socioeconomic status, and greater nutrition knowledge were more likely to rate as careful shoppers than those who had less education, lower socioeconomic status, and less nutrition knowledge.

The information developed in the 1975 survey on nutrition labeling is of special interest and importance to FDA and the food industry. (There was no data on this issue in the 1973 survey since FDA's nutrition labeling program was not officially underway until later.) About 60 percent of the shoppers interviewed said they had seen nutrition labeling and about one-third said they had actually used it. The data showed that a greater percentage of persons in

the younger age ranges made use of the labels than did older persons.

Education had a significant influence on whether a person used nutrition labels. (See Table 2.) Only seventeen percent of those with less than a high school education used the labels, compared to thirty-two percent for high school graduates and forty-two percent for college-educated shoppers. Shoppers with high socioeconomic status were more likely to use the labels than those with lower status. Non-blacks had more of a tendency to use nutrition labels than blacks. Among the people surveyed, those who scored high on nutrition knowledge and who were rated as careful shoppers were more likely to use nutrition labeling than those who did not score high on these factors.

These survey findings provide feedback to FDA's Bureau of Foods from consumers on trends in general shopping practices and on the extent to which nutrition labeling has become a useful aid to food shoppers.

Joseph Pearce is a consumer science specialist with FDA's Bureau of Foods.

FDA Goes On A Monomer Hunt

Everything that goes into food, even if it is only minute traces of the packaging material, is of concern to FDA. That's why the Agency's new Packaging Laboratory is taking a close look at the plastics and other substances in which food is bagged, boxed, bottled, canned or wrapped.

by Harold Hopkins

When we think about additives in food what we usually have in mind are substances intentionally added by the processor to perform various functions, such as to enhance flavor, change the texture or keep it uniform, raise or lower the acid content, retard spoilage, or regulate moisture content. These are called direct food additives.

Extensive publicity in recent times about the many additives put directly into food has diverted attention somewhat from another and larger class of additives which, along with direct additives, are subject to regulation by FDA and for the same reasons. This class is called incidental or indirect food additives—substances that get into food in small amounts, mainly from packaging materials and occasionally from production or processing equipment.

Indirect additives are permitted in food by law if FDA is assured that their use in the package will achieve the purpose intended, that they will have no functional effect in the food, and that they will not harm the consumer's health.

To help provide this assurance FDA has established a new laboratory. The Indirect Additives Laboratory (IAL), known more informally as the Packaging Laboratory, was established primarily to deal with nonfood substances

that may find their way into foods from the material of the packages in which they are canned, bottled, bagged, boxed, or wrapped. The laboratory opened for business two years ago at a time of rising concern at FDA about the possible effects on the consumer of eating or drinking small amounts of chemical substances that could migrate into food from packaging materials, including certain plastics, paper and paperboard, and coatings for the linings of metal cans.

One reason for such concern was widely publicized recently in a series of developments that included a proposal by FDA to prohibit the use of rigid and semi-rigid food packaging material in which vinyl chloride gas is a basic starting material. It was discovered in 1973 that, under some conditions, molecules of vinyl chloride, which is used to make polyvinyl chloride and other plastics and which had been thought previously to be chemically locked into the packaging material, could escape or migrate into the food. This discovery was followed by the more disturbing finding that vinyl chloride gas, if inhaled, can cause cancer (see *Polyvinyl Chloride: Why FDA Acted*, FDA CONSUMER, December 1975-January 1976). FDA now is taking a closer look at the potential for migration of other substances used in the production of plastic food packaging materials.

Like it or not, we're aswim in a plastics sea. From celluloid, the granddaddy of commercial synthetic plastics marketed over a century ago, has developed a family of substances that not only has improved the usefulness of but often replaces some of the traditional materials that provide us the stuff of civilized life: glass, clay, stone, metals and other minerals; gums, adhesives, and lubricants; and fibers such

as wood, cotton, flax, hemp, leather, fur, wool, hair, silk, and feathers. The outpour of plastics into our lives and our economy in the past few years has caused some sociological observers to refer to us as "the plastic society."

Plastics are made from small, simple molecules known as monomers. The chemical process of converting these monomers into plastic causes them to link together to form chains of larger molecules called polymers. Monomers that fail to link together to form polymers normally escape into the atmosphere, but some may be trapped in the plastic. If the plastic is used to package food, these trapped monomers may escape and migrate into the food, thus becoming potential sources of indirect food additives.

Under the law, the presence in food of an additive that has not been approved by FDA, or that is not generally recognized as safe, is illegal. Regulations permitting the use of specific additives are issued by FDA in response to petitions by persons who propose their use for commercial purposes. The law explicitly permits the use of such additives subject to whatever restrictions FDA may impose in the interest of consumer protection.

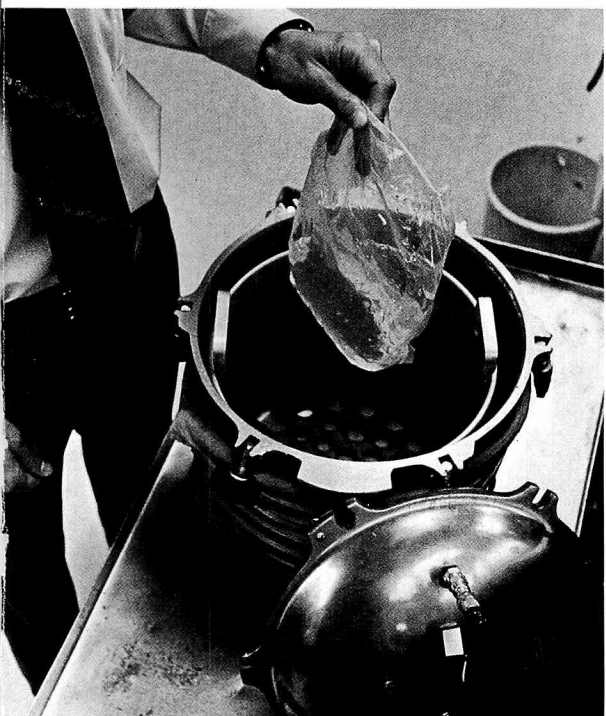
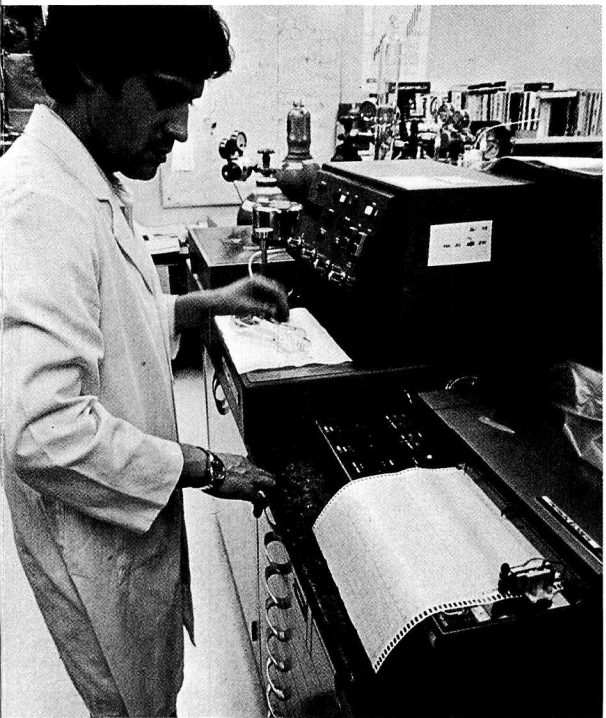
A food additive petition must state why and how the additive will be used, the identity of the additive, its chemical composition, and the process used to manufacture it. The amount of the additive permitted for direct use in food cannot exceed that needed to achieve the purposes of its intended use, and FDA may specify the maximum amount that can be present.

If approval is sought for a packaging material (an indirect additive), the petitioner also must describe methods that can be used to determine how much of the additive could possibly get into food. These techniques, called extrac-

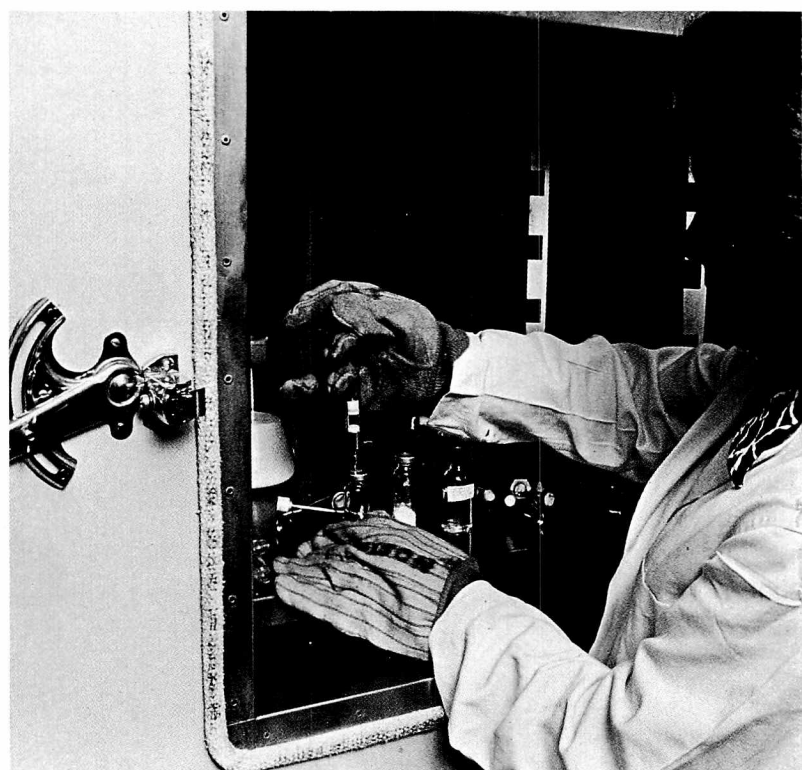
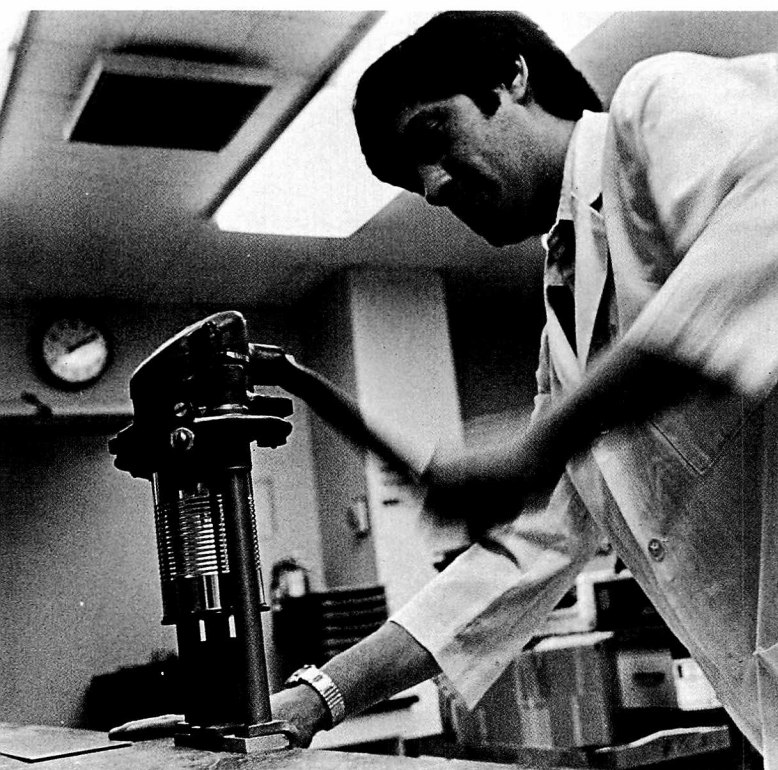
A differential scanning calorimeter is used by Chemist Tim McNeal to find the melting point of a plastic used in food packaging. This determination aids in identifying and characterizing the materials from which the plastic was made.

A pressure canner simulates commercial food processing conditions for testing a food pouch that can be heated to temperatures high enough to sterilize food. This is a new method of preserving food proposed by several manufacturers, but not yet approved by FDA. After the pouchful of food-simulating solvent is heated, the contents are assayed for migrated materials.

In examination of plastics to find if they contain polyvinyl chloride, the quick flame test can eliminate those that contain no PVC. A bright green glow, produced when a portion of a plastic canning jar lid gasket is placed on a copper rod and held over a bunsen burner flame, indicates PVC may be present. If the flame remains normal, the material definitely contains no PVC.



A series of procedures shows whether vinyl chloride will migrate from a polyvinyl chloride food wrapping material into a food-simulating solvent. Chemist Tim McNeal cuts a strip of the film from a commercially used roll, loops it around a roll of metal screen wire to keep the surfaces apart, and seals it in a metal can after first adding a food-simulating solvent. The can is stored several days at temperatures higher than normal use conditions, is then opened, and a portion of the liquid transferred to another container, and heated in an oven for 30 minutes. Chemist Margaret Brown removes part of the sample to inject it into a gas chromatograph for detection and measurement of any vinyl chloride present.



tion methods, usually involve bringing the proposed packaging material into contact with chemical solvents. The solvents used are ones that produce approximately the same effect on the material as the food that will be packaged in it.

The solvent used in the test is then analyzed to determine how much of the additive could get into (migrate to) the food. Different solvents, such as water, alcohol, acetic acid, or oils, are used to simulate the actions that different types of food would have on the packaging. The test material and the solvent may be shaken or otherwise agitated to simulate the conditions that actually occur in the day-to-day handling of packaged food.

FDA also may require the person or firm seeking approval of an additive to test it in laboratory animals to determine its effects. The results, including any unusual or adverse effects on the animals, are supplied to FDA for evaluation in deciding whether to issue a regulation permitting use of the additive.

FDA's requirements for packaging materials and processing equipment that may contribute indirect additives to food apply to products that are to be used in commercial establishments or in the home for food processing, storing, dispensing, or other functions. These might include, for instance, reusable food containers, and sandwich and freezer bags. FDA is just as concerned about additives that may become components of food in the home kitchen as about those that may enter food from commercial operations.

FDA traditionally has relied on a strong background of scientific information to support its decisions in behalf of consumer protection. In evaluating the safety and suitability of food additives the Agency has depended on scientific data supplied by petitioners and their reports of studies they conducted. Now, with establishment of the Indirect Additives Laboratory, FDA

has strengthened its own scientific capabilities in this area.

The Indirect Additives Laboratory has several functions. When petitions are submitted, it may conduct its own review of them as well as a laboratory evaluation of the analytical methods proposed by the petitioner for determining how much of the additive might get into the food. The laboratory's review also may include examination of samples of the material proposed to be used as packaging. This review process provides FDA with its own information to check against the accuracy of that filed in a petition.

The laboratory is responsible for developing or refining methods to identify monomers and other substances that may be present as potential additives. These methods are used to determine the content of monomers in various plastics and the amount of these monomers that can be extracted with food-simulating solvents. IAL also studies the potential for migration of substances to food from the various forms of packaging materials already approved by FDA, such as plastic coatings used to line the inside of food cans, plastic bottles and similar containers, plastic sheeting or film used for bags and other food wrapping packages, and plastic coatings on paper and cardboard used for bags or cartons.

The laboratory is collecting an inventory of food packaging materials and the chemicals used in their manufacture and carrying out research on special problems such as the recent one involving vinyl chloride. When called upon, the laboratory also helps FDA field facilities to solve problems associated with food packaging.

Since it began in 1974, the laboratory has concentrated on studies of vinyl chloride and more recently has been developing methodology for the measurement of another monomer, acrylonitrile. Acrylonitrile may be used in the manufacture of carbonated beverage bottles and many other articles

used with food.

One type of problem that emphasizes the need for laboratory capability at FDA to back up regulatory decisions concerns the variation that can occur in the manufacture of plastics and the effect this can have on their uses in food packaging. Samples of plastic materials submitted with petitions usually are prepared in relatively small quantities under strictly controlled test conditions.

When mass production for commercial use begins, the plastic produced may not be quite the same as the test sample originally submitted. This happens when unforeseen variations in plastic composition occur because of the complex nature of manufacture, when there is a need for several processing steps at different plants or companies, or when there is poor quality control. Any of these could result in manufacturing differences and an end product that does not comply with the appropriate food additive regulation and may not be safe to use. Periodic checking by the Indirect Additives Laboratory of materials on the market will help assure continuing compliance with the regulations affecting them.

The findings about migrations from some polyvinyl chloride food packaging materials and the safety questions that have arisen about them make it apparent that materials which have been approved must be subjected to a continuing evaluation as more sensitive analytical procedures and newer toxicological information become available. The Indirect Additives Laboratory, with its knowledge of the chemistry and technology of plastics and their uses in food packaging, is an important part of the plan to protect the consuming public because it gives FDA the ability to check petitions for new additive materials and to recheck those already on the market.

Harold Hopkins is editorial director of FDA CONSUMER

The Great Grain Rescue

by James Greene

When the largest grain elevator disaster in U.S. history threatened the loss of more than 5 million bushels of wheat, corn, and milo, Federal and State agencies and private industry launched a cooperative salvage effort.

A gap in a row of concrete silos (right) marks the spot where an explosion demolished the eight-story main grain elevator at the Goodpasture facility near Houston. The blast, which shot a 300-foot fireball skyward that could be seen and heard for miles around, lifted the roof off the main elevator, disintegrated half the exterior wall, dumped tons of grain and debris over a wide area, crushed the roofs of the round steel grain storage tanks at the left, and heavily damaged the steel warehouse that runs along the ship channel.

"It looked like a mushroom cloud." That's how charter pilot Roy J. Fassell described the rising column of smoke he saw when he piloted his light plane over the Goodpasture, Inc., grain elevator on the outskirts of Houston, where less than three minutes earlier an explosion had killed nine persons, injured seven, and showered tons of wheat and other grain over a wide area.

The explosion—the largest grain elevator disaster in U.S. history—destroyed the main elevator, a major loading point for grain shipments to Russia, and extensively damaged all but three of 12 storage tanks that ran in a row parallel to the elevator.

The blast—which is believed to have

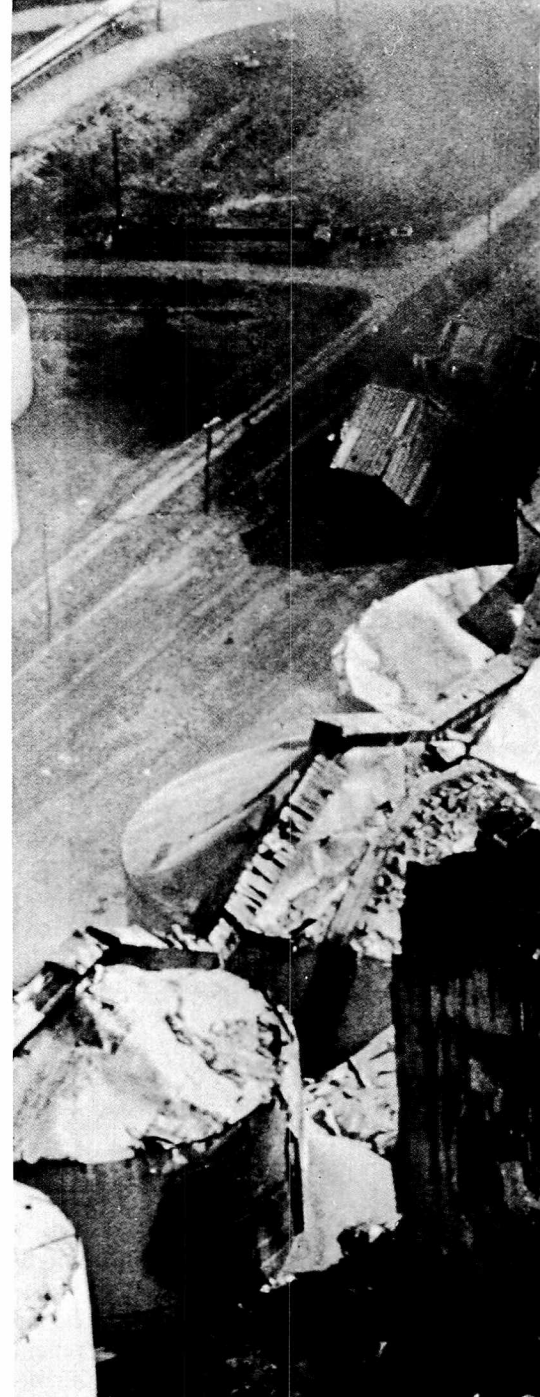
been set off when a fire in the upper levels of the elevator detonated grain dust—and the resulting fire that smoldered for more than a month caused an estimated \$42 million damage to the elevator and related facilities.

Over 17 million gallons of polluted water from the nearby Houston ship channel were pumped on the elevator and 11 storage bins to bring the huge fire under control. In all, over 5 million bushels of wheat, milo, and corn valued at about \$20 million were initially considered contaminated because of the channel water and the fire, smoke, and debris caused by the explosion.

The dust from the February 22 blast had hardly settled before FDA and

State of Texas officials were conferring with representatives of the Goodpasture facility and the salvage company to determine the best way to salvage as much of the grain as possible. It would be the largest grain salvaging effort ever attempted.

The first step was for the State to place all grain at the facility under an embargo. The grain varied in the amount and kind of contamination. Grain closest to the site of the actual explosion and fire generally was more heavily damaged than grain held in tanks away from the immediate blast area. FDA investigators and Texas State health inspectors worked side by side to examine grain samples for aflatoxin—a highly toxic substance





produced by some mold—filth, pesticides, heavy metals (actual debris from the blast), moisture content, bacteria, and smoke odor.

Whether the grain could be reconditioned for human or animal use depended on the presence of bacterial contamination or other health hazards and the degree of smoke contamination. Smoke contamination was determined by organoleptic field examinations performed by FDA and State personnel who smelled samples of the grain to detect smoke odor. Too strong an odor made the grain commercially objectionable for human use even if there was no health hazard involved. Examination of the grain samples for smoke odor and other contaminants

continued on a day-to-day basis for several months until the massive job of sampling all the grain exposed to the blast was completed.

Of the 5.3 million bushels stored at the facility at the time of the explosion, FDA and State personnel determined that over 600,000 bushels were a total loss. About 1.4 million bushels remained dry and free of contamination. This grain was moved to other local storage facilities to await export. Another 880,000 bushels required reconditioning for human use, and were transported via barges to two Louisiana reconditioning plants. The remaining 2.4 million bushels were contaminated but considered salvageable as animal food.

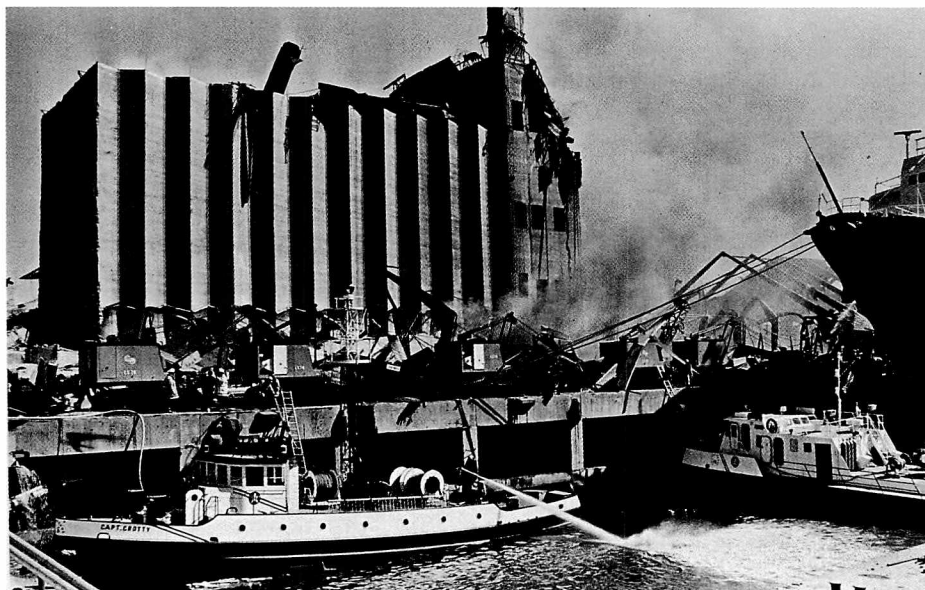
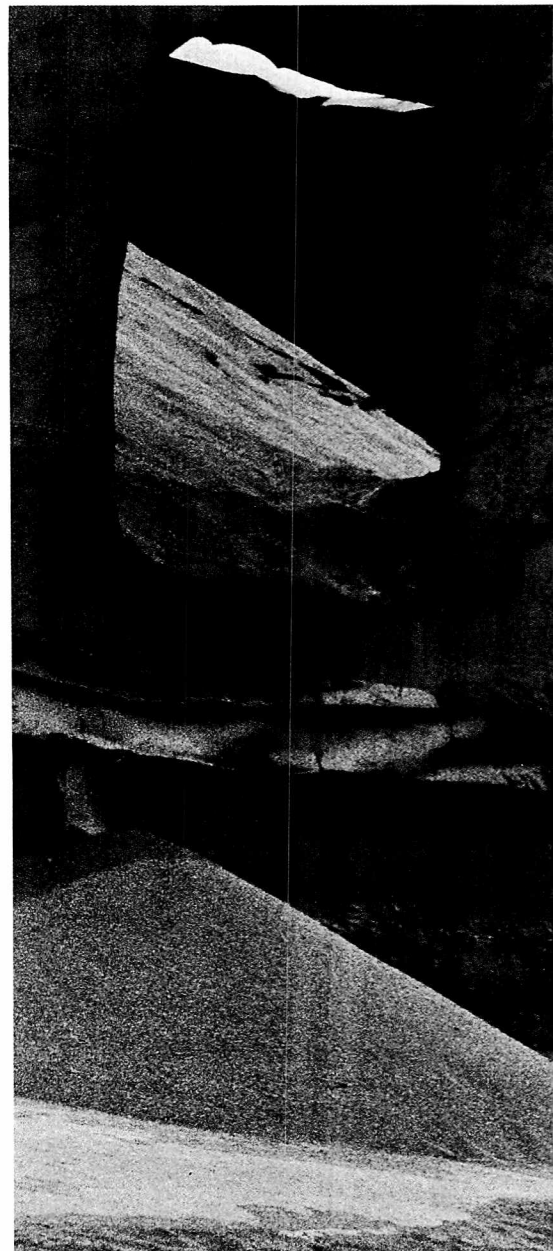
Because of the enormous volume of grain involved, and the destruction of the grain handling and storage facilities at Goodpasture, other facilities with reconditioning capabilities were needed. Nine facilities in Texas, Louisiana, Arkansas, Missouri, and Illinois were chosen to recondition the contaminated grain. These plants had the heat-treating equipment needed to kill bacteria and to prevent aflatoxin contamination, and all but the Arkansas facility and one facility in Louisiana had access to the Mississippi River which allowed the grain to be shipped via barges for reconditioning. The grain was moved to the Arkansas plant and one of the two Louisiana plants by truck.

Large holes had to be cut in the sides of steel storage tanks so front-end loaders could remove the grain for reconditioning.

Grain is sucked from a barge to a conveyor belt that will carry it to nearby storage tanks at the Tallulah Port Elevator in Louisiana. Barges were used to transport most of the grain to be reconditioned from the Goodpasture facility to plants located along the Mississippi River.

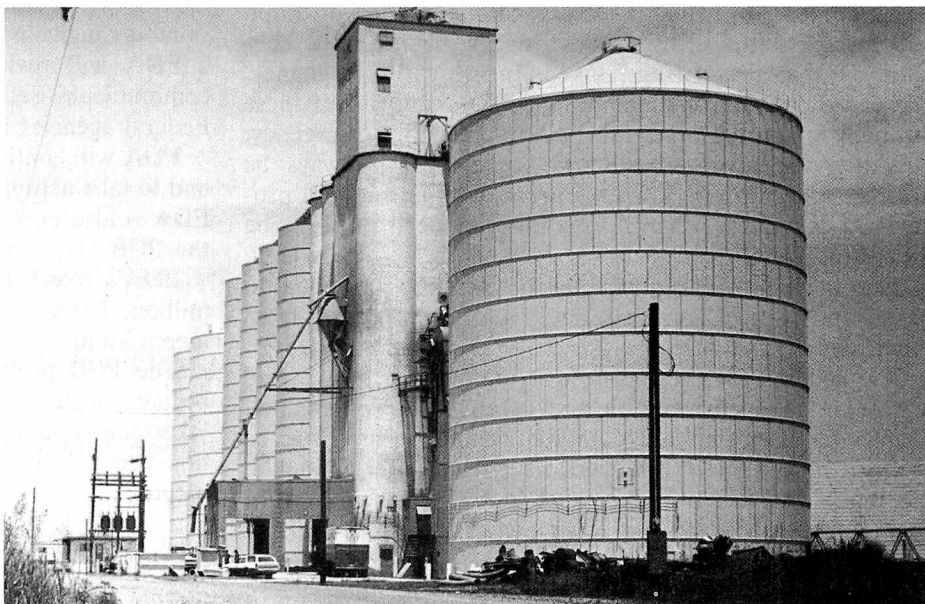
Some 850,000 bushels of grain were reconditioned at the Tallulah Port Elevator in Louisiana. The main elevator at Tallulah Port (bottom photo, right), in line with a row of silos, is similar to the Goodpasture elevator that was demolished by the explosion.

Fireboats (below), as well as land-based fire equipment, were used to fight the blaze at Goodpasture. Use of polluted water from the Houston ship channel by the fireboats contributed to the contamination of the grain.



Once the grain designated for use in animal feed reached the reconditioning plants, it underwent a cleaning process that included shaking and sifting to filter out large foreign particles caused by the explosion and fire; drying by heating to as much as 300° F. to prevent the growth of possible harmful bacteria and mold; and finally, analysis to double check that the grain was free of possible aflatoxin contamination.

Grain designated for human use underwent similar reconditioning with two important exceptions. It was shaken, sifted, and aerated over a longer time to allow maximum air exposure to help dissipate the smoke odor, and was heat treated at normal grain drying temperature for a shorter



period to reduce the moisture content.

Monitoring shipment of the grain to the reconditioning facilities and keeping tabs on it through the cleaning process and subsequent handling required constant communication between FDA's Houston office and Agency headquarters in Rockville, Maryland. Equally important was communication between FDA headquarters and the State health agencies which in most cases were holding the grain under State embargo and were sharing responsibility with FDA field personnel in monitoring the reconditioning.

As each shipment left the Goodpasture facility, the State of Texas lifted the embargo and the Houston FDA office provided FDA headquarters with

detailed information on each barge or truck number, its destination, how much grain was being transported, and the condition of the grain at the time of departure as determined by samples taken by FDA, the U.S. Department of Agriculture, and the Texas Department of Health.

This vital information was then relayed to the States through FDA's National-Regional-State-Telecommunication Exchange Network (NRSTEN). Its primary purpose is to provide information as quickly as possible to State agencies on potential health hazards associated with FDA regulated products. Some sixty telecommunication terminals in State agencies throughout the fifty States, the District of Columbia, and Puerto Rico provide

direct two-way communication between FDA headquarters, field offices, and selected State agencies.

"Only someone who saw the area right after the explosion can appreciate what an accomplishment it was to salvage almost 90 percent of the grain involved," said Dupre S. Spiller, Jr., FDA project coordinator in charge at the blast site. "This was the first big test of our new Federal-State communications system and it performed beautifully. But I think the main lesson to be learned from this effort is how much can be done when Federal and State governments and industry work together to achieve a common goal."

James Greene is a staff writer with FDA's Office of Public Affairs.

News Highlights

Pregnancy Warning Set for Tranquilizers

The Food and Drug Administration has ordered the manufacturers of the largest-selling tranquilizers to warn physicians that these drugs should almost always be avoided by women during the first three months of pregnancy.

Three recent studies indicate there may be an association between use of the tranquilizers in early pregnancy, and malformations such as cleft lip in babies.

The tranquilizers affected by the order are the drug meprobamate, best known by the brand names Miltown and Equanil, and a group of drugs known as the benzodiazepines, the most familiar of which are diazepam (Valium) and chlordiazepoxide (Librium). These drugs are widely prescribed for the relief of anxiety and tension. The warning will be required in the labeling of generic and brand-name versions of these drugs.

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, said: "The studies do not demonstrate conclusively that these drugs, taken during early pregnancy, can cause cleft lip or other birth defects. But use of these tranquilizers during pregnancy is rarely a matter of urgency, and their use during this time should almost always be avoided. The warning label we are now requiring will provide physicians with the information they need to prescribe these drugs safely."

The warning will appear in the labeling provided to physicians. It must appear in bold face type, set apart from other label warnings.

The labeling for these drugs for many years has carried a general statement that the use of any drug in pregnant women requires that the potential benefit of the drug be weighed against the possible hazard to the mother and child, but this is the first time the labeling will specifically warn against using these drugs during the first three months of pregnancy.

The new warning also will advise physicians that, before prescribing these tranquilizers for a woman of childbearing age, they should consider the possibility she may be pregnant.

The warning will further advise physicians to tell women of childbearing age that if they become pregnant or wish to become pregnant while taking these drugs, they should discuss with their physicians the desirability of discontinuing the drug.

FDA told the manufacturers they must add the warning to labeling within 60 days or at the next printing of the labeling, whichever comes first. FDA will withdraw approval of any drug that fails to carry the label warning. The order appeared in the *FEDERAL REGISTER* of Friday, July 23, 1976.

Michigan Issues Warning on Lake Fish

The State of Michigan has issued a press release saying that people who eat sports fish caught in Lake Michigan have more polychlorinated biphenyls (PCB's) in their blood than people who do not.

Polychlorinated biphenyls are industrial chemicals that are used for a variety of purposes.

The State made clear that the amount of PCB's found in the blood has not caused any detectable illnesses. But the State cautioned the public against eating more than one meal per week of Lake Michigan sports fish, especially coho, chinook, and steelhead and lake trout, and said pregnant women probably should not eat such fish at all.

The State based its report on a two-year study funded by FDA.

FDA endorses the action taken by the State of Michigan in warning the public about consuming sports fish caught in Lake Michigan.

FDA has been encouraging State governments to take action whenever significant problems of fish contaminated with PCB's are found. In February, FDA supported action by New York State to ban commercial fishing, except shad, from the Hudson River and to advise sportsfishermen to restrict their consumption of fish caught in the Hudson and salmon caught in Lake Ontario.

FDA will review further the Michigan data and will communicate details of the study to other States and to Federal agencies involved in controlling PCB pollution.

FDA will continue to encourage States to monitor PCB's and to take action whenever significant problems are found. FDA is also encouraging States to seek FDA assistance on the PCB problem when needed.

FDA's tolerance level for PCB's in fish is 5 parts per million. FDA will act against all fish in interstate commerce found to exceed that level.

The PCB problem in fish affects only fresh water fish because of the continued industrial discharge of PCB's into lakes and streams. Most fish intended for human consumption come from salt waters which have not been contaminated with PCB's.

Use of Chloroform in Drugs, Cosmetics Banned

FDA has banned chloroform as an ingredient in human drugs and cosmetics. The ban was based on a study by the National Cancer Institute which found that chloroform induces liver cancer in mice and kidney tumors in male rats.

Under the ban, which went into effect July 29, no drug or cosmetic product with chloroform as an ingredient may be shipped in interstate commerce. The ban had been proposed April 9, 1976. Virtually all manufacturers had stopped using chloroform before the ban took effect. Chloroform was used in liniments and as a flavoring agent in cough medicines and two toothpastes.

FDA Budget of \$245 Million Approved

A budget of \$245 million for the Food and Drug Administration for the fiscal year beginning October 1, 1976, has been approved by Congress and signed by the President. This represents an increase of more than \$35 million or 17 percent over the budget for fiscal year 1976.

The new budget authorizes 7,299 positions for FDA, an increase of 996 over fiscal year 1976. The bulk of the increases in money and positions are for two programs. An additional \$16 million and 606 new positions are autho-



rized to strengthen FDA's monitoring of industry testing of new drugs in animals and people, and an additional \$5 million and 319 positions are authorized to implement a new law giving FDA greater authority to regulate medical devices.

Courts Uphold FDA in Three Cases

Federal courts have upheld FDA's position in three major cases involving color additives, hypoallergenic cosmetics, and vitamins and minerals.

The U.S. Circuit Court of Appeals for the District of Columbia upheld FDA's ban on the use of the color additive Red No. 2 in foods, drugs, and cosmetics. The ban had gone into effect February 12, 1976. The case was brought by three manufacturers and one trade association which were seeking to overturn the ban. FDA banned Red No. 2 after concluding that existing tests could not demonstrate the additive's safety.

The U.S. District Court for the District of Columbia upheld FDA's hypoallergenic cosmetic regulations which define the term "hypoallergenic" and require that a manufacturer have scientific data to back up a claim of hypoallergenicity. The regulations define a "hypoallergenic" product as one which is less likely to cause adverse reactions than some competing products.

The regulations had been issued in final form in June 1975, but FDA stayed them pending resolution of the court case. The case was brought by Almay and Clinique, two cosmetic manufacturers.

The U.S. District Court for the Southern District of New York upheld FDA regulations requiring prescriptions for dosages of vitamin A over 10,000 International Units and vitamin D over 400 International Units. The court said that the Agency was acting within its authority in establishing those requirements.

Congress recently enacted a law forbidding FDA from setting limits on the maximum dosage of vitamins and minerals unless a health hazard is involved. Vitamins A and D have been shown to be highly toxic when used in large dosages.

Drug Reaction Monitoring System Planned

The Food and Drug Administration (FDA) and the National Bureau of Standards (NBS) have announced a million-dollar joint project to develop systems for monitoring newly-approved medicines for unwanted reactions. The systems would help FDA uncover previously unsuspected adverse effects more quickly than is now possible.

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, said: "Before FDA approves a new drug, it has been tested extensively in animals but at most in only a few thousand people. Once it is approved, the number of people who receive the drug often increases rapidly to many thousands. Some adverse effects are so rare they can be detected only after a drug has been used by many thousands of patients or for an extended time.

"For this reason, the first few years after a drug is ap-

proved is a time for special alertness and careful evaluation.

"This project will help FDA develop methods to make better and faster decisions on long-term drug safety and effectiveness," said the Commissioner.

"In addition," said Dr. Schmidt, "legislation now before the Congress would give FDA authority to require manufacturers to conduct post-marketing studies of new drugs. Clearly, we could make better use of such authority if we had effective drug monitoring systems. With NBS assistance, we will develop such systems."

NBS' Experimental Technology Incentives Program (ETIP) will provide \$1.1 million and expert advice for design of drug monitoring systems. FDA will develop and test the systems under one or more contracts to be awarded on a competitive basis.

Program Planned to Assure X-ray Quality

FDA has announced plans to develop recommendations for quality assurance programs in diagnostic x-ray facilities. The advance notice of intent to propose recommendations, published in the May 7, 1976 *FEDERAL REGISTER*, is one of a series of recommendations to be proposed by the Agency on the hazards and control of electronic product radiation or radiation from other sources.

The term "diagnostic x-ray facility" includes any facilities in which an x-ray system is used in a procedure that involves irradiation of any part of the human body for the purpose of diagnosis or visualization. Examples of such facilities are offices of individual physicians, dentists, podiatrists, and chiropractors, mobile laboratories, clinics, and hospitals.

"Quality assurance" is defined as planned, systematic actions that provide adequate confidence that an x-ray facility will produce consistently high quality radiographs at minimum cost and minimum patient exposure.

The experience of FDA's Bureau of Radiological Health, which administers programs involving devices that emit radiation, indicates that voluntary facility-based programs are the most promising way to assure consistent nationwide production of high quality diagnostic radiographs at minimum cost and minimum patient exposure.

Interested persons are invited to submit comments and suggestions on designing and implementing x-ray quality assurance programs. Information is also being sought on personal experience with facility-based quality assurance programs and on the cost versus the benefits of such programs.

Written comments should be submitted to the office of the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20852. The closing date for filing comments is November 3, 1976.

To assist those facilities wishing to start their own quality assurance programs the Bureau of Radiological Health is compiling a catalog of information on test devices and procedures, training materials, and pertinent publications and articles. Companies, institutions, or individuals wishing to contribute to the catalog may write to the Hearing Clerk, at the above address, for further information.

Regional Reports

"Regional Reports" consists of important information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA's regional and district field offices across the country to provide protection to consumers under Federal laws. "State Actions," the section immediately following "Regional Reports," consists of similar information about the consumer protection activities of State and local governments.

REGION II

New Jersey, New York, Puerto Rico

The Federal Government seized 188 lots of food products, most of which were spices and edible seeds, at Gardner Brooklyn Warehouse, Inc., Brooklyn, because of rodent infestations. The seizure resulted from an inspection by investigators from FDA's **New York District** who received an anonymous telephone call alerting them to the rodent problem.

Swordfish containing levels of mercury in excess of 0.5 parts per million—the maximum amount permitted by FDA—was quickly removed from the market through cooperative action of FDA's New York and Orlando District offices and the New York City Health Department. Surveillance by the Orlando District revealed that the swordfish—caught along the coast of the western Florida Panhandle and suspected of containing high levels of mercury—was being trucked to markets in the Northeast. Alerted that a shipment was enroute to the Fulton Fish Market in Manhattan, New York District investigators were waiting to collect samples of the fish when the truck arrived at dawn. The New York City Health Department placed the fish under embargo while the samples were analyzed by the New York

District laboratory. One lot, valued at \$2,000, was found to contain an average of 0.8 parts per million of mercury and was voluntarily destroyed by the wholesale dealer.

It might have been sweet, but it wasn't honey. That was the finding of the New York District laboratory after chemists analyzed samples of 117,000 pounds of a product labeled as pure honey and offered for import at the Port of Buffalo by Butland International Corp., Toronto, Canada. The shipment, valued at \$34,000, was refused entry by FDA's **Buffalo District**. Chemists testing for product acidity and for such natural components as proline, lactone, and potassium, determined that the shipment, which supposedly originated from Iran, was not pure honey, as the shipper claimed.

A shipment of bloody mary cocktail mix, valued at about \$5,000 and offered for import from Powell Foods, St. Catharines, Ontario, Canada, was refused entry into the Port of Buffalo after Buffalo District investigators discovered rodent filth in the bottles during a routine inspection. The shipment consisted of 1,300 cases of 24-ounce bottles and was destined for a firm in Stamford, Connecticut.

Pasta, offered for import from Italy, was refused entry at the ports of Albany and Buffalo by Buffalo District investigators who discovered, during a routine import inspection, that the \$13,000 worth of fettucini, tortiglioni, and other macaroni products contained insect and rodent filth. The pasta was made by Joly SNC of Treviso, Italy.

The Delson Candy Corp., Englewood, New Jersey, recalled and destroyed more than 70,000 pounds

of mint candies after investigators from FDA's **Newark District** discovered, during a routine inspection, that the firm was using a green color that contained Red No. 2, a color additive recently banned by FDA. Specific products recalled were Delson Merri-Mints, green Merri-Mints, green Mint Thins, and Newton Cream Mints. Packages containing mints of assorted colors were reconditioned by the company by removing and destroying all the green-colored candy. FDA supervised the reconditioning.

The Federal Government seized approximately one million pounds of animal feed and raw material at Provimi, Inc., Flanders, New Jersey, after Newark District investigators found evidence of rodent contamination in \$250,000 worth of medicated milk replacers for veal calves. Medicated milk replacers make up the complete diet for milk-fed veal calves, and Provimi, Inc., currently produces approximately fifty percent of the milk replacers on the market. During the routine inspection investigators also found evidence of rodent adulteration in the production and storage areas.

REGION IV

Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee.

FDA's **Atlanta District** supervised the voluntary destruction of 55,000 pounds of potatoes in Charlotte, North Carolina, after laboratory tests revealed rodent hairs on the potatoes, as well as rodent-gnawed potatoes. The potatoes were being transported by Southern Railroad and were enroute from Quincy, Washington, to a food wholesaler in Hickory, North Carolina. The firm refused to accept the potatoes and then notified FDA's Atlanta District, which carried out an

examination of the potatoes in the railcars.

Lee Laboratories, Inc., Grayson, Georgia, has voluntarily suspended the manufacturing of reagents used in the grouping and typing of blood until its operations are brought into compliance with FDA's regulations relating to the manufacture and distribution of such biological products. The suspension was the result of an inspection by the Atlanta District at the laboratory where investigators discovered deficiencies in records used to prepare, control, and distribute blood serums, as well as failure of the firm to obtain the required clearance from FDA's Bureau of Biologics before relocating some of its operations.

The major portion of a shipload of green coffee beans, offered for import from Madagascar, was refused entry into the United States at the Port of Jacksonville, Florida, after an inspection by FDA's **Orlando District** revealed the coffee was rodent contaminated. The shipment consisted of nearly three million pounds of coffee and was valued at over \$1.8 million. The remaining coffee, which was not inspected at Jacksonville, was offered for import at New York City, where it was detained by FDA's New York District.

A total of four hundred and sixty-five pounds of natural apricot kernels, valued at approximately \$950, was destroyed by a U.S. marshal in a city dump in Jacksonville, Florida, after FDA laboratory tests revealed that a sample of the kernels contained the poisonous substance hydrogen cyanide in a quantity which could be injurious to health. The sampled kernels were obtained by FDA's **Jacksonville Resident Post** and the entire lot was subsequently seized at Tree of Life, Inc., a health food store supplier in St. Augustine, Florida. Apricot kernels are used as a source of Laetrile, which sometimes is sold under the name Vitamin B-17. Laetrile has long been promoted and sold to the public for the prevention or cure of cancer. Laetrile has no formal recognition as a vitamin, and FDA is not aware of any scientific proof that it prevents or cures cancer in animals or humans.

This was the Federal Government's first seizure of apricot kernels based on the fact that FDA considers them unfit for human consumption due to the presence of toxic levels of hydrogen cyanide.

Deputy U.S. marshals seized two types of electric panels—one for human use, the other for use on horses—from the distributor, Bio-Lectron Products, Hollywood, Florida, after an investigator from FDA's **Louisville Resident Post** inspected a Kentucky-based firm which manufactures the devices and determined that the labeling of the devices was false and misleading. The labeling of the human device claimed that it supplied negative electrons to the body which restored the body's electrical balance, and in turn, relieved pain and anxiety, cured insomnia, prevented arthritis, bursitis, backaches, nervous tensions, and accelerated the body's healing process. The labeling for the horse device suggested it would cure or mitigate arthritis, bursitis, sinusitis, thrush, bowed tendons, and wobbles, leg troubles, and stiffness and soreness. Marshals seized 33 Bio-Lectronic panels for humans, valued at nearly \$5,000, and three Bio-Lectronic panels for horses, valued at approximately \$2,000. The inspection at the Louisville manufacturing firm, Solarama of Kentucky, Inc., which led to the Florida seizure of the devices and about 19,000 accompanying booklets was the result of an inquiry to the Louisville Resident Post from a consumer reporter for WHAS-Television news in Louisville.

REGION V

Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin.

Over \$2 million worth of food products were seized by a U.S. marshal at the J. Winkler & Sons, Inc., Warehouse, Dale, Indiana, following an inspection by FDA's **Detroit District**. Investigators found the products, which included sugar, instant mashed potatoes, cake mixes, packaged coconut, and dog food, were stored under insanitary conditions and contaminated with rodent excreta. Inspectors from the Indiana Board of Health originally discovered the rodent contamination,

and after repeated warnings to the firm to take corrective action went unheeded, requested FDA to perform its own inspection.

Mammoth Spring Canning Corp., Oakfield, Wisconsin, has entered into a consent decree in the U.S. District Court for the Eastern District of Wisconsin which will allow for the reconditioning of 1,770 100-pound bags of red kidney and pinto beans under FDA supervision. The action resulted from a series of inspections by investigators from FDA's **Minneapolis District** who determined that the beans, with a wholesale value of \$50,000, were being held in a rodent-infested warehouse.

A joint investigation by FDA's **Cincinnati District** and St. Louis Resident Post resulted in Federal Government seizure of a tablet press, a set of press dies, and a drug mixer, at the C. M. Bundy Co., a drug manufacturer in Cincinnati, Ohio. The Government alleges that the equipment was used to manufacture counterfeit drugs, which were allegedly being distributed in the St. Louis area.

REGION VII

Iowa, Kansas, Missouri, Nebraska.

L & B Corp. doing business as Millard Warehouse at two locations in Omaha, Nebraska, pleaded guilty to one of four charges of holding 2,200 pounds of raisins under insanitary conditions in a rodent-infested warehouse, and was fined \$500 by Judge Albert G. Shatz of the U.S. District Court of Nebraska. The corporation's president, Larry Larsen, pleaded no contest to the same charge and was fined \$100. The other three counts were dismissed by the judge at a pre-trial hearing when the corporation and its president changed their initial plea of not guilty. The court action resulted from a series of inspections at the warehouse by FDA's **Omaha Resident Post**.

REGION IX

Arizona, California, Guam, Hawaii, Nevada.

A lot of 7,500 pounds of frozen shrimp, offered for import from

Kwong Commercial Co., Makati, Philippines, was detained by FDA's **San Francisco District** after laboratory examination determined the shrimp was decomposed. The lot, consigned to a warehouse in Davis, California, was being stored in a frozen food warehouse in Santa Clara, California. The detention was the result of a routine FDA import inspection.

A lot of 19 cases of acrid-sweet pickles, valued at \$145, from Bangkok, Thailand, was seized by a U.S. marshal at Eastimpex Agency, an import food wholesaler in San Francisco, after swollen and leaking cans were discovered during a routine import inspection by investigators from FDA's San Francisco District. Another lot shipped earlier to Tucson, Arizona, by Eastimpex was reshipped back to San Francisco under FDA supervision where it was subsequently seized for the same reason.

During a routine inspection of the Luce Candy Co., Los Angeles, by FDA's **Los Angeles District**, an inspector observed a loose-fitting cover on a bulk corn syrup storage tank. Because the tank was located outside the plant,

the inspector removed the cover to check the contents and discovered numerous insects floating in the syrup. The firm voluntarily destroyed approximately 4,000 pounds of contaminated syrup and installed new fittings to prevent future problems with insects.

Victor Loaiza, chief of the Pesticides Department in Mexico's Department of Agriculture, and two other Mexican agriculture officials visited the Los Angeles District to receive orientation on FDA's laboratory and inspection work relating to pesticides. Such cooperation is designed to help prevent problems with illegal pesticide residues on produce imported into the United States from Mexico.

REGION X

Alaska, Idaho, Oregon, Washington. Six investigators from FDA's **Seattle District** office, in cooperation with other Federal agencies and State and local health departments, monitored food and drug salvage operations in six Idaho cities following the collapse of the Teton Dam on the Snake River in early June. The 307-foot-high, earth-filled dam collapsed, sending a

wall of water 15 feet high and 10 miles across down the Snake River Valley. The cities of Rexburg, Sugar City, Roberts, Lewisville, Riverside, and Blackfoot sustained damage from the flood waters. The monitoring activities involved the segregation and destruction of flood-damaged stocks at 159 firms engaged in the commercial handling of food and drugs. Millions of pounds of potatoes at several processing plants in the area were either reconditioned or destroyed. An estimated \$3.7 million worth of various food and drug products was destroyed.

A consumer complaint led to the seizure of 31 cases of imported corn by a U.S. marshal in Portland, Oregon. The consumer reported that upon opening a jar of the corn it "fizzed like a bottle of pop that had been shaken." Subsequent investigation and examination of samples by FDA's Seattle District showed that the product was unfit for food because of swollen jar lids, and a cloudy precipitate in the packing medium. The corn had been imported, packed, and distributed by Paradise Packing Co., Brooklyn, New York.

State Actions

Bottler Pays \$10,000 Penalty

National Drinks Bottling Co., San Diego, California, has agreed to pay \$10,000 in civil penalties in the Superior Court of San Diego after the California Health Department initiated a civil lawsuit charging the company with allegedly selling soft drinks containing foreign substances which included glass, mold, and insect fragments. The firm, without admitting guilt, agreed to the out-of-court settlement. The suit resulted from insanitary conditions discovered during an inspection of the plant conducted by State inspectors under a contract with FDA. In March, the firm, again without admitting guilt, paid a fine of \$20,000 for similar alleged violations

at its Gardena facility. The San Diego plant bottles Hires Root Beer, Dr. Pepper, and Canada Dry soft drinks.

Pimientos Destroyed

A health official of the Pennsylvania Department of Agriculture witnessed the voluntary destruction of 200 cases of East Winds brand canned pimientos at a landfill dump near Pittsburgh after State health analysts determined the acidity of the pimientos was too low. Too little acidity in pimientos can lead to the growth of *Clostridium botulinum*, an organism that causes botulinal poisoning. The pimientos, imported from Spain by Connel Rice and Sugar Co., and valued at nearly \$6,000, were embargoed by the State

of Pennsylvania at Mallet's Gateway Terminal Number Two, Inc., a warehouse in Pittsburgh, after State health inspectors discovered that some of the cans were swollen.

Warehouse Firm Fined

J. C. Curry & Co., Inc., Birmingham, Alabama, a food storage warehouse, pleaded guilty to seven counts of food adulteration and was fined \$1,500 by U.S. Magistrate Edwin L. Nelson of the U.S. Court for the Northern District of Alabama. The rodent-adulterated foods included pinto beans, flour, and salt. Inspectors from FDA's Birmingham Resident Post inspected the firm after a State inspection found violative conditions.

Seizures and Postal Service Cases

SEIZURE ACTIONS charging violation of the Federal Food, Drug, and Cosmetic Act are published when they are reported by the FDA District Office.

A total of 17 actions to remove from the consumer market products charged to be violative was reported in June. These included 10 seizures of foods involving charges concerning contamination. Other seizures included 1 of food additive, 1 of color additive, 3 of drugs (including 1 for veterinary use), 1 of prophylactic, and 1 of cosmetic/beauty product.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
FOOD/Contamination, Spoilage, Insanitary Handling		
Apple juice, canned/Fairfield, Ohio 6/3/76	Shipped from Hart, Mich.	Decomposed; swollen cans.
Coffee beans/Dallas, Tex. 5/24/76 New Orleans, La. 3/19/76	Imported from Mexico. Hansen & Tidemann, Inc./New Orleans, La. (D)	Held under insanitary conditions. Held under insanitary conditions; bird contami- nated.
Cornmeal, coffee beans/New Orleans, La. 6/29/76	Strachan Shipping Co./New Orleans, La. (D)	"
Oats, rolled/Ann Arbor, Mich. 6/10/76	Eden Foods, Inc./Ann Arbor, Mich. (D)	Rodent contaminated.
Potatoes, dried/Chicago, Ill. 4/1/76	Hammond Refrigerated Warehouse/ Chicago, Ill. (D)	Held under insanitary conditions.
Salmon, canned/Wilmington, Calif. 5/14/76	Frosty Fish Co./Wilmington, Calif. (P)	Decomposed.
frozen/Wilmington, Calif. 5/14/76	Astoria Fish Factors/Astoria, Oreg. (S)	"
Los Angeles, Calif. 5/17/76	"	"
Shrimp, frozen/Warren, Mich. 4/9/76	Ben Kozloff, Inc./Chicago, Ill. (S)	"
FOOD ADDITIVE		
Sodium pangamate/Deer Park, N.Y. 6/3/76	Edom Labs., Inc./Deer Park, N.Y. (D)	Contains the nonconforming food additive sodium pangamate; false and misleading claims concern- ing nutritional value, identification and safety; lacked common or usual name of all ingredients.
COLOR ADDITIVE		
Olender's Dark Red color, amaranth color/Hamtramck, Mich. 6/23/76	Philip Olender & Co./Hamtramck, Mich. (D)	Contained Red No. 2 (amaranth) after color was delisted.
DRUGS/Human Use		
Hydrogenated ergot alkaloid tablets, imipramine HCl tablets & raw material/Copiague, N.Y. 5/12/76	Bolar Pharmaceutical Co., Inc./ Copiague, N.Y. (M)	Lacked adequate directions for use and not ex- empted since no approval of New Drug Appli- cation.
Injectable drug stocks/Queens Village, N.Y. 3/12/76	Torigian Laboratories/Queens Village, N.Y. (M)	Production and holding lacked conformity with current good manufacturing practice.
Veterinary/Medicated Feed		
Triple-bolic injection, Tri-gom oil injection, dexamethasone sodium phosphate injection/Fort Collins, Colo. 4/22/76	Anthony Products Co./El Monte, Calif. (S); Cromalloy Pharmaceuti- cals, Inc./Glendale, Ariz., and/or DM Pharmaceuticals, Inc./Rock- ville, Md. (S)	New animal drugs for which no approved New Animal Drug Application was effective.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
Prophylactics		
Prophylactics, rubber/St. Louis, Mo. 3/18/76	Circle Rubber Co./St. Louis, Mo. (P)	Contain holes.
COSMETIC/BEAUTY PRODUCT		
Medicated skin cream/St. Louis, Mo. 4/15/76	Lander Co., Inc./St. Louis, Mo. (M)	Production and holding lacked conformity with current good manufacturing practice.

U.S. POSTAL SERVICE actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Chief Postal Inspector.

Complaints Filed by Law Department Under 39 U.S.C. 3005 (False Representation)

- April 8, 1976: **Chris Sales**, P.O. Box 85097, Los Angeles, California 90072. Advertising and sale through the mail of the product "Linga Pendulum," representing the ability to increase the size of the penis and cause a stronger and stiffer erection.
- April 8, 1976: **Erotic Book Club**, P.O. Box 35301, Los Angeles California 90035. Advertising and sale through the mail of the product "Linga Pendulum," representing the ability to cause a stronger and stiffer erection.
- April 13, 1976: **Diverse Industries**, 7651 Haskell Avenue, Van Nuys, California 91406. Advertising and sale through the mail of alleged "love potions," representing the ability to cause sexual desire and ability in the user.
- April 20, 1976: **United Electics**, 1645 Alawai Boulevard, #1002, Honolulu, Hawaii 96815. Advertising and sale through the mail of a booklet which describes a plan representing the ability to cure cancer.
- April 28, 1976: **M & M Enterprises**, 324 So. First Street, Alhambra, California 91802. Advertising and sale through the mail of the product "Diaxesrutan," representing the ability to restore lost and increase present ability to attain an erection, and reduce premature ejaculation.
- April 30, 1976: **Helen**, Box 5309, and **Helen K. Johnson**, 2700 Neilson Way, Santa Monica, California 90405. Advertising and sale through the mail of an alleged weight loss method, representing the ability to cause weight loss without the use of willpower.
- April 30, 1976: **Mexican Joe**, 256 So. Robertson Street, Beverly Hills, California 90213. Advertising and sale through the mail of the product "Doped Chewing Gum Nuggets," alleged aphrodisiacs, representing the ability of a sexual stimulant in younger women.
- May 3, 1976: **Miss Linda**, Suite 307, 6355 Topanga Blvd. Woodland Hills, California 91364. Advertising and sale through the mail of the product "Nymphos," alleged aphrodisiacs, representing the ability to "turn-on" women.
- May 7, 1976: **Grapefruit Growers, Sunny Hills Diet, and Mail Order Services**, 1818 West Chapman Avenue and P.O. Box 5900, Orange, California 92668, and 107 Water Street, Henderson, Nevada 89015. Advertising and sale through the mail of the product "Grapefruit Pill," representing the ability to cause a fast weight loss.
- May 18, 1976: **Long 'N Strong**, Caroline Road, Philadelphia, Pennsylvania 19176. Advertising and sale through the mail of a liquid to be brushed on fingernails, representing the ability to penetrate the fingernails to cause them to become longer and stronger, in a matter of days.
- May 18, 1976: **American Consumer**, Caroline Road, Philadelphia, Pennsylvania 19176. Advertising and sale through the mail of the STS Plan, representing the ability to cause weight loss while sleeping, without the need to restrict food intake, and without the use of willpower.
- May 18, 1976: **United Gifts**, STS Plan, 741 Main Street, Stamford, Connecticut 06904. Advertising and sale through the mail of the STS Plan, representing the ability to cause weight loss while sleeping, without the need to restrict food intake, and without the use of willpower.
- May 20, 1976: **Revel Company**, P.O. Box 2856, Sepulveda, California 91343. Advertising and sale through the mail of the product "Linga Pendulum," representing the ability to enlarge the user's penis and strengthen the user's erections.

False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005

- April 5, 1976: Against **Cecily Vane**, GPO Box 239, Boston, Massachusetts 02101. Advertising and sale through the mail of a pamphlet entitled "New Miracle Bustline Plan," representing the ability to transform flat bustlines into bigger, tauter, shaplier measurements; increase the bustline and firm up sagging breasts.
- April 14, 1976: Against **Rogers Labs, Inc.**, 15383 N.W. 7th Avenue, Miami, Florida 33169. Advertising and sale through the mail of the product "Prostaid," allegedly containing vitamins and mineral capsules, representing the ability to relieve the pain and discomfort associated with benign prostate conditions.
- April 15, 1976: Against **Slender Magic**, 600 By Pass Road, Clearwater, Florida 33516. Advertising and sale through the mail of an alleged reducing method representing the ability to cause weight loss and loss of girth without dieting or exercise, solely by means of mental process.
- April 21, 1976: Against **Nina of Germany**, 256 S. Robertson Street, Beverly Hills, California 90213. Advertising and sale through the mail of the product "Long Dicking Cream," representing the ability to increase the length of the penis and insure sexual conquest.
- April 28, 1976: Against **United Medical Supply**, P.O. Box 4823, North Hollywood, California 91607. Advertising and sale through the mail of the product "Commander," a male genital device representing the ability to effect or enhance the erection of the penis.
- April 28, 1976: Against **Male Personal Products**, P.O. Box 285, Hollywood, California 90028. Advertising and sale through the mail of the product "Vim," representing the ability to enlarge the user's penis, and restore lost or increase present sexual desire and ability.
- May 3, 1976: Against **Successful Living Center**, 9622 Vons, Garden Grove, California 92642. Advertising and sale through the mail of a cassette tape recording representing the ability to cause weight loss by making your body conform to your mind's self-image.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions FOOD/Contamination, Spoilage, Insanitary Handling

Anchovy fillets, canned, at Bristow, N. Dist. Okla.

Charged 8-28-75: while held for sale, the article contained decomposed anchovy fillets and was contained in swollen and leaking cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60454; S. No. 76-14-952; N.J. No. 1)

Brazil nuts, shelled, at White Pigeon, W. Dist. Mich.

Charged 1-23-76: while held for sale, the article contained rancid nuts; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 60626; S. Nos. 76-21-425/6; N.J. No. 2)

Candy pacifiers, Lic-A-Nip, at Sacramento, E. Dist. Calif.

Charged 4-9-75: when shipped by The Paul Spitz Co., Inc., Bronx, N.Y., the article was unfit for food, since it was prepared in a manner and in a shape which presented choking and aspiration hazards to infants and small children who were likely to use the article; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60319; S. No. 30-060 H; N.J. No. 3)

Cheese, Swiss, at Smithfield, Dist. Utah.

Charged 10-9-74: while held by Cache Valley Dairy Association, Smithfield, Utah, who manufactured the cheese, the article contained the nonconforming food additive, motor oil (that had dripped from an overhead manufacturing vat agitator); and the article was unfit for food due to the presence of motor oil; 402(a)(2)(C), 402(a)(3). The dealer claimed the article, asserting that tests had been conducted which showed no evidence of motor oil content, that such food additive, if it existed at all, existed in such exceedingly small quantities that the article was not unsafe, and that the beneficial use should not be prevented. Subsequently, a consent decree ordered destruction. (F.D.C. No. 59946; S. No. 79-891 H; N.J. No. 4)

Clam-fry mix, wheat flour, and rye flour, at New Bedford, Dist. Mass.

Charged 9-24-75: while held for sale, the clam-fry mix and wheat flour contained rodent and/or insect filth, and all the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60485; S. No. 76-05-724; N.J. No. 5)

Coffee beans, at New Orleans, E. Dist. La.

Charged 4-29-76: while held by Strachan Shipping Co., Inc., New Orleans, La., the article contained bird filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60704; S. No. 76-37-950; N.J. No. 6)

Flour, whole wheat, at Peoria, S. Dist. Ill.

Charged 2-12-76: while held for sale, the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60645; S. No. 76-10-001; N.J. No. 7)

Fruitcakes, at Davenport, S. Dist. Iowa.

Charged 8-27-75: while held for sale, the article contained mold; 402(a)(3). Consent decree authorized release to Bonnie Bakeries, Davenport, Iowa, for salvaging. (F.D.C. No. 60460; S. Nos. 76-25-004/7; N.J. No. 8)

Mushrooms, marinated, at Laredo, S. Dist. Mex.

Charged 9-12-75: while held for sale, the article was contained in glass jars with swollen and leaking lids; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60461; S. No. 87-921 H; N.J. No. 9)

Peanuts, unshelled, Parker Packt, at Salt Lake City, Dist. Utah.

Charged 4-21-75: while held by Western Nut Co., Salt Lake City, Utah, the article was held under insanitary conditions;

402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60373; S. No. 79-969 H; N.J. No. 10)

Popcorn, at Greeley, Dist. Colo.

Charged 10-10-75: while in transit in an insect-infested truck after rejection by Arrow Industries, Carrollton, Tex., the article contained insect filth, and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to D & D Bean Co., Greeley, Colo., for salvaging. (F.D.C. No. 60503; S. No. 76-15-469; N.J. No. 11)

Popcorn, yellow, at Lawrence, Dist. Mass.

Charged 1-15-76: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60622; S. No. 76-57-184; N.J. No. 12)

Popcorn, yellow, at Mobile, S. Dist. Ala.

Charged 2-3-76: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60624; S. No. 76-44-079; N.J. No. 13)

Popcorn, white, at Baltimore, Dist. Md.

Charged 1-26-76: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60625; S. No. 76-03-892; N.J. No. 14)

Poppyseed and sesame seed, at Roxbury, Dist. Mass.

Charged 12-9-75: while held by Kasanof's Baking Co., Inc., Roxbury, Mass., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60565; S. No. 76-05-400; N.J. No. 15)

Potatoes, scalloped, at Monroe, W. Dist. La.

Charged 12-22-75: while held by Ritchie Grocery Co., Monroe, La., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60594; S. No. 76-38-581; N.J. No. 16)

Pudding, chocolate, canned, Del Monte, at Hato Rey, Dist. P.R.

Charged 1-22-76: when shipped by the Del Monte Corp., San Francisco, Calif., the article was unfit for food due to a soapy taste; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60617; S. No. 76-50-418; N.J. No. 17)

Rice, at Milwaukee, E. Dist. Wis.

Charged 1-23-76: while held by the Dernehl-Taylor Co., Milwaukee, Wis., the article had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60629; S. Nos. 76-31-447, 76-31-450; N.J. No. 18)

Rice, onion toast rounds, plain toast rounds, and orange gelatin, at Evansville, S. Dist. Ind.

Charged 1-23-76: while held by the Federal Produce Co., Inc., Evansville, Ind., the articles were held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60593; S. Nos. 76-18-648/51; N.J. No. 19)

Rice, brown, at Hereford, N. Dist. Tex.

Charged 2-10-76: while held by Arrowhead Mills, Inc., Hereford, Tex., the article was held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60633; S. No. 76-14-580; N.J. No. 20)

Shrimp, frozen, at Oakland, N. Dist. Calif.

Charged 10-6-75: when shipped by Penguin Frozen Foods, Inc., Port Isabel, Tex., the article, labeled in part "Penguin Brand Green Headless . . . Packed By Valley Frozen Foods, Inc. Port Isabel, Tex.," contained insect filth, and shrimp heads, crab shell fragments, and fish had been substituted in part for headless shrimp; 402(a)(3), 402(b)(2). Default decree ordered destruction. (F.D.C. No. 60483; S. No. 76-48-523; N.J. No. 21)

Shrimp rolls, frozen, Flavos, at Mechanicsville, E. Dist. Va.



Charged 8-18-75: when shipped by Flavo-Rite Foods, Inc., Bronx, N.Y., the article contained *E. coli*, and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Richfood, Inc., Mechanicsville, Va., claimed the article, stated that it lacked the knowledge or information to form a belief as to the truth of the charge, and stated that it neither admitted nor denied that the article was liable to seizure and condemnation. The Government moved for summary judgment detailing in an attached affidavit and in attached FDA records the results of the scientific tests and the conditions under which the article was prepared and packed. Upon consideration of the Government's motion (no response having been received from the claimant), the court condemned the article and ordered it destroyed. (F.D.C. No. 60428; S. No. 112-735 H; N.J. No. 22)

Teas of comfrey root, and of yarrow flowers, at Burbank, C. Dist. Calif.

Charged 1-23-76: while held for sale, the articles contained insect filth; 402(a)(3). Consent decree authorized release of comfrey root tea to Cal Leaf Products of Burbank, Calif., for salvaging. Default decree ordered destruction of yarrow flowers tea. (F.D.C. No. 60631; S. Nos. 76-27-621/2; N.J. No. 23)

Tomato puree, at Northlake, N. Dist. Ill.

Charged 1-12-76: when shipped by the Home Canning Co., Blissfield, Mich., the article, labeled in part "Railton Natural Brand, Midwestern, Tomato Puree . . . Distributed by B. A. Railton Co., Northlake, Ill.," contained mold; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60600A; S. No. 76-10-157; N.J. No. 24)

Wheat, at Murray, Dist. Utah.

Charged 8-15-75: when shipped by Howard Petracek, Jennings, Kans., the article, which was in 60-lb. bags labeled in part "Granulated Sugar Net Wt. 100 Pounds Holly Sugar Corporation—Colorado Springs, Colorado," "Graham—C 100 LBS. Net Wt. Mfg. By Nabisco, Inc., Carthage, Mo.," and "Morton . . . Coarse Salt . . . Net Wt 80 LBS. Morton Salt Company Chicago, Ill.," contained rodent filth; and such label statements were false and misleading since the article was wheat, the manufacturers, packers, or distributors were not those named on the labels, and the bags did not contain 80 or 100 pounds of products; 402(a)(3), 403(a). Consent decree authorized release to Gar-Low, Inc., Murray, Utah, for reprocessing into animal feed. (F.D.C. No. 60441; S. Nos. 76-11-802/3; N.J. No. 25)

FOOD/Economic and Labeling Violations

Relish, sweet, Paramount, at Nashville, M. Dist. Tenn.

Charged 1-12-76: when shipped by Paramount Foods, Inc., Louisville, Ky., the article was approximately 2.7 percent short in volume; 403(e)(2). Consent decree authorized release to shipper for bringing into compliance. (F.D.C. No. 60608; S. No. 76-33-309; N.J. No. 26)

Shrimp, breaded, frozen, Ocean Supreme, at Cookeville, M. Dist. Tenn.

Charged 12-2-75: when shipped by Variety Frozen Foods, Inc., Tampa, Fla., the article failed to conform to the definition and standard of identity for frozen raw breaded shrimp, since the article tested less than 50 percent shrimp material; 403(g)(1). Default decree authorized donation to a charitable institution. (F.D.C. No. 60554; S. No. 76-34-101; N.J. No. 27)

DRUGS/Human Use

Decongestant tablets, at Norfolk, E. Dist. Va.

Charged 2-4-76: while held by Coastal Pharmaceutical Co., Inc., Norfolk, Va., who had repacked some of the bulk article into bottles labeled in part "C.P.C. Plus Decongestant Phenylephrine HCl 5 mg. Phenylpropanolamine HCl 25 mg. Chlorpheniramine Maleate 2 mg. Ascorbic Acid 60 mg . . . Mfg. for Coastal Pharmaceutical Co., Inc. Norfolk, Va.," the article's strength differed from its represented strength, and the declared amount of phenylpropanolamine hydrochloride was false and misleading, since the article contained approximately 70 percent of such declared amount; 501(c), 502(a). Default decree ordered destruction. (F.D.C. No. 60638; S. Nos. 76-03-277, 76-04-004;

N.J. No. 28)

Oxygen for medical use, at Marion, N. Dist. Ohio.

Charged 1-8-76: while held by DeLille Oxygen Co., Marion, Ohio, the circumstances of the article's manufacture, processing, and packing failed to conform to current good manufacturing practice; 501(a)(2)(B). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 60597; S. No. 76-12-250; N.J. No. 29)

Plasma, salvage, at Syracuse, N. Dist. N.Y.

Charged 1-20-76: when shipped by McDonough County Blood Bank, Macomb, Ill., the article's label lacked the name and place of business of the manufacturer, packer, or distributor, lacked any quantity of contents statement, and lacked the established name of the drug (i.e., "salvage plasma," or "human plasma (salvaged)"); and the article's labeling lacked adequate directions for use, since it failed to indicate that the article was suitable for use as an *in vitro* reagent not subject to licensing and was not suitable for use as or in biological products subject to licensing; 502(b)(1), 502(b)(2), 502(e)(1)(i), 502(f)(1). Default decree ordered destruction. (F.D.C. No. 60619; S. No. 76-07-510; N.J. No. 30)

Various drug stocks, at Dallas, N. Dist. Tex.

Charged on or about 2-11-76: while held for sale after being subjected to abnormal environmental conditions and fires in December 1972 and December 1974, the circumstances used for the holding of the article failed to conform to current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 60553; S. No. 76-14-900 et al.; N.J. No. 31)

Viro-Zyme sodium nucleate combination injectable and Lipo-K pancreas extract and chondroitin sulfate combination injectable, at New Rochelle, S. Dist. N.Y.

Charged 12-23-75: when returned from Muskogee, Okla., to the manufacturer, Marcen Laboratories, Inc., New Rochelle, N.Y., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (F.D.C. No. 60577; S. No. 76-16-101; N.J. No. 32)

MEDICAL DEVICES

Diapulse electromagnetic energy generator, at Waynoka, W. Dist. Okla.

Charged on or about 9-16-74: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., the labeling of the article lacked adequate directions for use for its intended purposes, since neither adequate directions for lay use nor adequate information for use by licensed practitioners could be furnished; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 59974; S. No. 90-897 H; N.J. No. 33)

Diapulse electromagnetic energy generators, at Lexington, E. Dist. Ky.

Charged 9-20-72: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the labeling of the articles lacked adequate directions for use for the articles' intended purposes and neither adequate directions for lay use nor adequate information for use by licensed practitioners could be prepared; 502(f)(1). No claim to the articles was filed, and accordingly, a default decree of condemnation was entered. Subsequently, Rovel C. Choate, D.P., Lexington, Ky., moved to set aside that default decree. The court set aside the decree on the ground of excusable neglect, and allowed the parties to file memoranda relating to questions raised by the court as to the propriety of a default decree of condemnation in this action. The claimant was allowed to file a claim to the articles, and an answer to the charges. The claimant admitted that the device did not bear adequate directions for use, but asserted that the devices were exempted by regulation (21 CFR 1.106(d)). The claimant served written interrogatories on the Government. In May of 1974, the parties agreed to an order submitting the case "for final determination as presently constituted subject to the answers supplied by the plaintiff to the interrogatories." In August of 1974, the parties filed cross-motions for summary judgment. The District court granted the claimant's motion for summary judgment saying:

"On the basis of the pleadings and supporting papers filed



herein, both parties have moved for summary judgment, claiming that there is no material issue of fact and that each is entitled to judgment as a matter of law. . . .

"It is important at the outset to delineate the issue raised on the cross[-]motions.

"The government does not dispute that the machines are prescription devices; it does not allege that the machines are harmful in any wise or that they present a hazard to the public when used by a practitioner licensed to use them; and it does not deny that they are beneficial and helpful when used by such licensed practitioner.

"The sole basis for plaintiff's motion is that the machines are misbranded * * * in that their labeling fails to bear adequate directions for use, and the articles are not exempt from such requirements under regulation 21 CFR 1.106(d)."

"Claimant asserts, as grounds for its cross-motion, that the machines comport with the aforesaid regulations. Thus, the case, as plaintiff acknowledges, 'comes down to the single narrow issue of whether the seized devices comply with 21 CFR 1.106(d)."

"The undisputed facts of record establish that claimant is a licensed doctor of Physio therapy, having been issued, on February 23, 1939, a license to practice Physio therapy by a duly constituted licensing board of the Commonwealth of Kentucky, and that he has been duly and regularly engaged in the practice of Physio therapy, also known as Physio therapeutics, for over 30 years in that state up to the present time. . . .

"The record also establishes that in 1963, after first thoroughly testing the Diapulse machines, by leasing one of the devices and examining the results of its uses, claimant became convinced of their merit as an aid in the treatment of certain ailments and diseases, and purchased the three machines at bar. The devices, which have been used regularly by claimant since 1963, were found to be particularly and peculiarly effective in the treatment of arthritis, sprains, strokes and a variety of other ailments not susceptible to treatment in any other manner known to him. * * *

"The patients treated by claimant with the Diapulse device include prominent jurists, attorneys, doctors and professional people. They include, but are not limited to, Judges H. Church Ford and Chester Adams of Georgetown and Lexington, Kentucky, respectively (both since deceased, presumably of natural causes); Judge Robert Stephens, Lexington; Dr. Wm. R. McGee, Lexington; Col. Harland Sanders, Shelbyville, Kentucky; Ben L. Kessinger and Robert M. O'Dear, practicing Kentucky attorneys; and James L. Clay, attorney, Kentucky (deceased, presumably of natural causes). Counsel for claimant has been treated with the devices for low back arthritis and has found that, while claimant does not allege that the machines are a cure for arthritis, the pain and disability for that malady have been greatly alleviated by such treatments. Furthermore, counsel's wife, who has suffered from a cerebral accident, more commonly characterized as a stroke, has been receiving corrective therapy, including treatments with the devices, to reduce the effects of the stroke. The use of the devices in connection with her therapy and in treatment of a sinus condition has proved to be beneficial and effective.

"Turning to the issues raised on the motions for summary judgment, it is noted at the outset that there is no genuine issue as to any material fact.

"The burden is upon the libellant to show that claimant's devices are not in compliance with the provisions of the Food, Drug and Cosmetic Act. . . . Furthermore, libellant must establish its contention by a fair preponderance of the evidence. . . .

"The exemption for prescription devices from the labeling requirements of 21 U.S.C. 352(f)(1) is conditioned in the first instance upon the device being in the possession of a practitioner licensed by law to use or order the use of such device and sold to him for use in the course of his professional practice. 21 CFR 1.106(d)(1)(a) and (b). * * *

"The regulations also provide that the prescription device must bear a label cautioning that federal law restricts the device to sale by or on the order of a practitioner licensed by the law of the state in which he practices to use or order the use of such device. 21 CFR 1.106(d)(2)(i).

"The government claims noncompliance with this provision,

and cites an affidavit, dated June 22, 1974, submitted by an investigator with the Food and Drug Administration, Department of Health, Education and Welfare, wherein he states that he had visited claimant's premises on August 11, 1972 and had observed that the devices did not bear the aforesaid cautionary labels. * * *

"While not denying that the aforesaid [cautionary] labels [restricting the devices to licensed practitioners] are now affixed [The court had ordered a recess to give counsel an opportunity to examine the machines, which were but a short distance away, and report back to it.] to the devices, libellant appears to take the tack that, regardless of the circumstances of the particular case, prescription devices must at all times bear the cautionary labels and that, if detached even for a brief period of time, they will lose the benefits of the exemption allowed for such devices. This rigid approach is a form of technical pettifoggery that is arbitrary and unreasonable in carrying out the statutory purpose. Regulations promulgated pursuant to statute should be construed by administrative agencies in a manner that is reasonable and in harmony with the spirit and intent of the law. Accordingly, each case must be examined in light of the facts and surrounding circumstances to ascertain if the regulations have been complied with.

"The record shows that the Diapulse machines were shipped to claimant bearing the required labels; that they now bear such labels; that the labels were detached from the articles during a period in August 1972; and that, at all times, from their receipt in 1963 up to the commencement of this action, they were in the possession and custody of a practitioner licensed by the law of the state of Kentucky, wherein he practices, to use or order the use of the devices. On the foregoing facts, I find that there has been effective compliance with 21 CFR 1.106(d)(2)(i).

"Plaintiff also claims that the requirements of 21 CFR 1.106(d)(3), (4) and (5), *supra*, have not been met in that the Diapulse devices do not bear, nor are they accompanied by, any labeling providing information for their use. Section 1.106(d)(3), however, contains a proviso that such information may be omitted from the dispensing package—'if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device'.

"The 'directions commonly known' proviso was recently construed by the Tenth Circuit in *United States v. An Article of Device . . . KUF Diatherapuncture*, 481 F.2d 434 (10th Cir. 1973). * * *

"The machines in the aforesaid case apparently involved some form of acupuncture, a method of treatment which has gained only limited acceptance by the medical community of this country in recent years. Accordingly, the findings of the trial court [that the machines did not come within the exemptions], which were affirmed on appeal, with respect to the 'commonly known' proviso were entirely appropriate under the circumstances.

"Plaintiff relies herein upon the affidavits of two doctors, David B. Stevens, an orthopedic surgeon of Lexington, Kentucky, who is familiar with and has used the Diapulse device, and William D. Paul, a specialist in physical medicine and rehabilitation, who practices in Iowa and is not familiar with the Diapulse machine, to establish that the articles at bar are not 'commonly known' as required by the regulations. However, both affidavits indicate that, unlike the aforesaid acupuncture machines, the use of diathermy or diathermy-type machines is not unknown to or even uncommon in the medical profession in this country.

"I am unable to accept as a certainty, on the basis of the affidavits herein, that the seized articles are devices for which hazards, warnings and other information are not commonly known to practitioners licensed by law to use them. The court is not bound to accept the opinion of expert witnesses as conclusive. . . . Accordingly, I find that the government has failed to prove by a fair preponderance of the evidence that the Diapulse devices are not in compliance with 21 CFR 1.106(d)(3), (4) and (5).

"The conditions required to obtain an exemption having been fulfilled, claimant's motion for summary judgment is granted."



The Government appealed. The Court of Appeals reversed the judgment of the District Court, and remanded the action for entry of a judgment overruling the claimant's motion and granting the Government's motion for summary judgment. In its opinion, the Court of Appeals said:

"The government argues that the [district] court misconceived its function in considering the cross-motions for summary judgment. . . .

"In response, claimant argues that the 'agreed order' of May 24, 1974, converted the cross-motions for summary judgment into motions for judgment on an agreed submission, entitling the court to make findings of fact on any disputed factual questions.

"We believe that claimant's contention is without merit. The parties expressly referred to Rule 56 in their respective motions for summary judgment. Neither referred to the order of May 24. Thus it appears that the parties in effect waived or abandoned the stipulation contained in the May 24 order and elected to invoke summary judgment procedure.

"The function of a motion for summary judgment is not to permit the court to decide issues of fact, but solely to determine whether there is an issue of fact to be tried. . . . It follows that the district court's consideration of the preponderance of the evidence in ruling on the cross-motions for summary judgment was erroneous.

"Instead, the district court should have required the party moving for summary judgment to bear the burden of clearly establishing the non-existence of any genuine issue of fact material to a judgment in his favor. . . .

"Claimant concedes that the critical issue centers around the proviso to the third condition for the exemption:

[21 CFR 1.106(d)](3) . . . Provided, however, that such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

"In support of its motion for summary judgment, the government presented the affidavits of two physicians, both of whom stated that the directions for use of the devices 'are not commonly known [by] practitioners who are licensed by law to use the devices.' In considering these affidavits, the district court stated:

I am unable to accept as a certainty, on the basis of the affidavits herein, that the seized articles are devices for which hazards, warnings and other information are not commonly known to practitioners licensed by law to use them. The court is not bound to accept the opinion of expert witnesses as conclusive.

We are aware that courts are not generally required to accept, without more, the bare opinions of expert witnesses. In the present case, the affidavits of the two physicians, when read in their entirety, are not merely bald assertions of opinions but rather are statements of the witnesses relevant to the factual issue of whether directions for use and warnings as to the hazards involved are commonly known among practitioners licensed to use the devices. Although the physicians did give their opinions, the opinions were accompanied by statements of the physicians' qualifications and other facts on which the opinions were based.

"On the other hand, claimant made no showing that directions for use of the devices were commonly known to practitioners licensed to use them. Instead, claimant presented affidavits showing at best that claimant had used the devices to administer 125,000 treatments over a long period of years without any adverse side-effects. On appeal, claimant insists that his use of the device for a long period without any adverse effects is sufficient to satisfy the exemption provisions of the regulations because the purpose of the statute is to exempt labeling which 'is not necessary for the protection of the public health.' 21 U.S.C. § 352(f)(1).

"Assuming that claimant has used the device for a long period without adverse effects, this assumption alone in no

way suggests that the information for use of the device is commonly known by practitioners licensed for its use. We are not free to disregard the plain meaning of the regulation or the undisputed affidavits of the government that information for use of the device is not commonly known by practitioners licensed to use it.

"We have considered other contentions raised on appeal and find them to be without merit.

"The judgment of the district court is therefore reversed, and the action is remanded to that court for entry of judgment overruling the claimant's motion for summary judgment and granting the government's motion." (F.D.C. No. 58278; S. No. 2-506 F et al.; N.J. No. 34)

NOTICES OF JUDGMENT on Criminal Actions FOOD

Acri Wholesale Grocery Co., Joseph D. Acri, president, and Anthony Acri, vice president, Des Moines, S. Dist. Iowa.

Charged 4-9-74: all-purpose flour, brown sugar, enriched bleached flour, and granulated sugar were held in a building accessible to rodents and all the articles, except the granulated sugar, were contaminated with rodent filth; 402(a)(3), 402(a)(4). The defendants pleaded not guilty and consented to be tried by a U.S. Magistrate. The case came on for trial by the magistrate. After five days of trial, the magistrate found the defendants guilty on all counts, fined the corporation \$1,000 and each individual \$100. The defendants appealed their conviction to the District Court. Upon appeal, the District Court affirmed the convictions, saying:

"The relevant facts are as follows: In July and October of 1973, inspectors from the Food and Drug Administration (FDA) conducted extensive inspections of the Acri Wholesale Grocery Company warehouse in Des Moines, Iowa. The inspections were conducted during normal business hours. At both inspections, the FDA inspectors presented credentials and a written notice of inspection to Anthony Acri. Further, all indications pointed to routine inspections for contaminated or adulterated foodstuffs. The inspectors were occasionally accompanied by Anthony Acri or other employees on inspection tours of the warehouse. Photographs were taken by the inspectors at both inspections and a stroboscopic light source was utilized for photographs of the warehouse interior. No clandestine measures were taken by the inspectors to hide their photographic activities. The photographs depicted conditions existing inside and immediately adjacent to the exterior of the warehouse, including areas from which the inspectors obtained testing samples. These samples were taken from food substances, usually flour and sugar, which appeared to the inspectors to be contaminated by rodents. Receipts for all samples taken by the inspectors were given to Anthony Acri; and written reports of warehouse conditions, as observed and recorded by the inspectors, were given to Anthony Acri following both inspections.

"Generally, relations between the FDA inspectors and defendants Joseph and Anthony Acri were cordial and business-like. Anthony Acri acknowledged to the inspectors that the warehouse had some rodent control problems, and elicited suggestions from the inspectors on efficient methods to deal with the problems. In some instances, Acri followed these suggestions, including weed clearance and contracting with a rodent extermination company.

"Analysis of the samples obtained in the warehouse showed the existence of cat and rodent urine, excrement and hair in most of the flour and sugar samples. The inspectors also reported live and dead rodents and a live cat in the warehouse and around lots of foodstuffs. High weed growth was observed outside the warehouse which, according to the inspectors, substantially contributes to rodent infestation by providing nesting areas. Several of the inspectors testified that, in their opinion, the Acri warehouse was one of the most rodent[-]contaminated warehouses they had ever inspected.

"A report of the samples analysis was not given to defendants until approximately two to four weeks prior to trial, although Anthony Acri indicated to the inspectors that he desired an analysis report fairly soon after the inspections. However, about three weeks after the October inspection, a notice of condemna-



tion of certain food lots was served upon defendants and the lots were destroyed. Most of the allegedly contaminated food lots were voluntarily destroyed by the defendants during the inspections.

"On appeal to this Court, the defendants assign as error the following issues: 1. The introduction at trial of photographs taken by the FDA inspectors during the warehouse inspections. 2. The FDA's failure to furnish the defendants with portions of the samples taken from the warehouse and a copy of the sample analysis results. 3. The trial court's denial of the motions for judgment of acquittal by Joseph Acri and Anthony Acri. The motions asserted the lack of personal responsibility of these individual defendants for the actions of the corporation.

I. PHOTOGRAPHS

"The defendants initially contend the trial court erred in admitting into evidence photographs taken during the inspections. In the first instance, defendants argue that the photographs were taken without their permission and are, therefore, inadmissible because the photographic activities were outside the scope of 21 U.S.C. § 374(a) (1970). . . . Pursuant to Section 374(a), a flexible standard of 'reasonableness' defines the contours of an FDA inspection. Cf. *Durovic v. Palmer*, 342 F.2d 634 (7th Cir. 1965). The Court believes, under the circumstances present in this case, the photographing of warehouse conditions by FDA agents was not unreasonable. The agents were in the warehouse pursuant to lawful authority and following all procedural requirements mandated under Section 374, *supra*. Further, although it is an unnecessary basis for an inspection, the defendants fully consented to the inspections by FDA. See *United States v. Del Campo Baking Mfg. Company*, 345 F.Supp. 1371 (D. Del. 1972). The photographs were taken as part of the inspection, and the inspectors made no efforts to conceal the fact that photographs were being taken. Moreover, in this case the photographs introduced into evidence at trial were merely cumulative of the inspector's testimony regarding the insanitary conditions in the warehouse.

"Defendants also argue their rights under the Fourth Amendment to the United States Constitution were violated by the inspectors' photographic activities which exceeded their statutory authority. However, as previously discussed, the FDA agents were properly acting pursuant to statutory procedures. Assuming *arguendo*, the photographing of evidence in this case is a 'search and seizure' under the Fourth Amendment, the Court believes that once the validity of the inspection is established, the propriety of a photographic 'search' is co-extensive with the validity of the inspection. Cf. *Carter v. Beto*, 426 F.2d 242 (5th Cir. 1970). The Court therefore finds that the inspection was conducted pursuant to proper authority, and that no illegal or unwarranted intrusion resulted from the photographic activities.

"Finally, it is asserted by the defendants that they should have been given *Miranda* warnings prior to any photographic activities. The Court finds this contention meritless. Defendants were neither in 'custody' nor deprived of their freedom at any time in question. See *United States v. Thriftmart, Inc.*, 429 F.2d 1006, 1011 n.6 (9th Cir. 1970), *cert. denied*, 400 U.S. 926; *United States v. Del Campo Baking Mfg. Company*, *supra*. Moreover, and contrary to defendants' contention, there is no evidence of record that the focus of the Government's intent in inspecting the warehouse had, at any relevant time, shifted from a mere inspection to a criminal investigation.

II. SAMPLES AND ANALYSES

"The defendants also complain that the FDA agents did not furnish them portions of the samples taken from the warehouse or provide a copy of the sample analyses results. Sections 372(b) and 374(d) of Title 21, United States Code, defendants contend, require the FDA to provide these items, and a failure to provide sample portions or analyses results is jurisdictional to any prosecution under the Act. The Government claims that no request was made for sample portions, and that under Section 374(d), the Government need not provide warehouse owners with analyses results. . . .

"Defendants admit no request was formally made for portions of the samples, and the Court finds no error in FDA's failure to provide the sample portions. Furthermore, the Court finds that absent some formal 'request,' as obviously contem-

plated by the statute, the Government did not err in failing to provide sample portions.

"The defendants further argue that they were 'lulled' by FDA agents into believing that a copy of the analyses results would be provided to them [pursuant to the pertinent statutory provision, Section 374(d)]. . . . The Government contends the conspicuous absence of the term 'warehouse' in subsection (d), unlike the preceding subsections of Section 374, evinces a Congressional intent to exclude warehouses from the assay analysis provision contained in subsection (d).

"Although a careful reading of both Section 374 and its legislative history strongly supports the Government's contention, the Court believes it unnecessary to determine the issue on this basis. Rather, by defendants' own admissions, they received a copy of the assay results several weeks prior to trial. In the absence of a showing of some prejudice, this is sufficient. Moreover, assuming defendants were entitled as a matter of law to a copy of the results but had not received them, they would still be required to show that their 'ability "to make a complete defense" was prejudiced thereby.' *United States v. Cassaro, Inc.*, 443 F.2d 153, 157 (1st Cir. 1971), *quoting, Triangle Candy Co. v. United States*, 144 F.2d 195, 199 (9th Cir. 1944). The defendants have failed to show any prejudice occasioned by their failure to receive either the sample portions or the assay results.

III. PERSONAL RESPONSIBILITY

"Joseph Acri and Anthony Acri claim their motion for acquittal should have been granted because of their lack of personal responsibility for the corporate actions resulting in this criminal prosecution.

"In *United States v. Dotterweich*, 320 U.S. 277 (1943), the United States Supreme Court held that the Food, Drug, and Cosmetic Act 'dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.' *Id.* at 281. The Court went on to state that culpability under the Act is shared 'by all who . . . [have] a responsible share in the furtherance of the transactions which the statute outlaws.' *Id.* at 284.

"The content of the *Dotterweich* case was recently reappraised and upheld by the Court in *United States v. Park*, 421 U.S. 658 (1975). . . .

"The substantial weight of evidence in this cause clearly establishes the requisite 'responsibility and authority' of the individual defendants. Both Joseph Acri and Anthony Acri were officers of the corporation; both were key employees and daily operatives of the firm's activities; both gave orders to the work crews and generally supervised the warehouse work during the day and evening shifts. Anthony Acri, whose title was vice-president and warehouse superintendent, stated to an FDA inspector that he was responsible for building maintenance. Joseph Acri, a part-owner and president of the corporation, stated at trial that he was 'in a responsible position for running that whole business, not only the warehouse, but the office, the buying, the selling, the bank statements. I am in charge of running the whole business.'

"The Court believes the evidence adduced at trial substantially supports the trial court's finding of defendants' personal liability. See *United States v. Park*, *supra*; *United States v. Cassaro, Inc.*, *supra*, 443 F.2d at 157.

"Accordingly, there being no error of record in this cause, the judgment of conviction heretofore entered by the United States Magistrate is affirmed." (F.D.C. No. 59244; S. No. 46-724 G et al.; N.J. No. 35)

Daffin Mercantile Co., Inc., Panama City and Marianna N., Dist. Fla. Charged 5-9-75: cake mix was held in a building at Marianna, Fla., that was accessible to insects, and the cake mix was contaminated with insect filth; and egg noodles and popcorn were held in a building at Panama City, Fla., that was accessible to insects and rodents, and the egg noodles were contaminated with insect filth; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 60012; S. No. 749 G et al.; N.J. No. 36)

Edelman Bros. Baking Co., Inc., and **Robert Edelman**, vice president, Garfield, Dist. N.J. Charged 7-31-74: flour was held under insanitary conditions in



a building accessible to rodents and insects and was exposed to contamination by rodents and insects; 402(a)(4). Guilty pleas; fines. (F.D.C. No. 59349; S. No. 55-272 F et al.; N.J. No. 37)

Goodman Produce Co., Inc., and Jack Goodman, president, **William Goodman**, vice president, and **Paul Clark**, general manager, Dallas, N. Dist. Tex.

Charged 9-4-75 by grand jury: potatoes (counts 1 and 3), coconuts (count 2), and squash (count 4), were held in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty pleas, to counts 1-4 by corporation, to counts 1 and 2 by William and Jack Goodman, and to count 1 by Paul Clark; fines. (F.D.C. No. 60015; S. No. 37-737 H et al.; N.J. No. 38)

George W. Groetsch, t/a George W. Groetsch Wholesale Grocer, New Orleans, E. Dist. La.

Charged 9-27-74 by grand jury: all-purpose enriched flour, plain enriched flour, grits, instant oatmeal, and baby cereals were held in a building accessible to insects and rodents; and all of the articles, except the plain enriched flour, contained insect and/or rodent filth; 402(a)(3), 402(a)(4). Guilty plea as to the two counts involving flour, and nolo contendere plea as to the other three counts; fine, suspended imprisonment and probation. (F.D.C. No. 59734; S. No. 53-966 H et al.; N.J. No. 39)

Marbo Quality Foods, Inc., Fresno, E. Dist. Calif.

Charged 10-24-74 by grand jury: Marbo long grain rice was held in a building accessible to rodents and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Nolo contendere plea; fine. (F.D.C. No. 59704; S. No. 90-197 G; N.J. No. 40)

Northville Laboratories, Inc., and Gerry A. Kraus, vice president & secretary, Northville, E. Dist. Mich.

Charged 10-11-75: dried buttermilk was held in a building accessible to rodents, and was contaminated with rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Nolo contendere plea by individual; fine. (F.D.C. No. 60439; S. No. 10-976 H; N.J. No. 41)

I. & B Corp., t/a Millard Warehouse, and Larry A. Larsen, president & treasurer, Omaha, Dist. Nebr.

Charged 3-17-76: raisins were held in a building accessible to rodents and were exposed to contamination by rodents; 402(a)(4). The defendants pleaded not guilty and moved for discovery of the Government documents related to the action. The parties litigated such discovery. Subsequently, the defendants changed their pleas. Guilty plea by corporation; fine. Nolo contendere plea by individual; fine. (F.D.C. No. 60005; S. No. 78-106 H; N.J. No. 42)

Little Dutch Boy Bakeries, Inc., William W. Morris, president, **Alfred J. Taggard**, vice president, and **Frank Bakker**, vice president, Draper, Dist. Utah.

Charged 9-26-75: dried sweet whey and sugar were held under insanitary conditions in a building accessible to rodents and were exposed to contamination by rodents; cookies (containing the component shortening shipped in interstate commerce) were prepared, and packed into boxes, in insect-infested equipment in an insect- and rodent-infested building; and cookies, labeled in part "Little Dutch Boy Home Style Cookies Baked by Little Dutch Boy Bakeries, Inc., Draper, Utah . . . Fancy Dutch Cookies [or 'Chocolate Chip']" and "Flavor Kist Assorted Dutch Cookies . . . Dist. by Schulze and Burch Biscuit Co., Chicago, Ill.," had been prepared and packed under insanitary conditions; 402(a)(4). The defendants pleaded not guilty. The corporation changed its plea to guilty and was fined. The case against the individuals came on for trial before court and jury. After the presentation of the Government's case, the defendants moved to dismiss the charges. As to Morris and Taggard, all counts were **dismissed**. The court denied the motion to dismiss as to Bakker. At the conclusion of the trial, the jury returned a verdict of **not guilty** as to Bakker. (F.D.C. No. 60265; S. No. 62-858 H; N.J. No. 43)

Mississippi Bayou Crab Co., and Doyle W. Bell, president, Pascagoula, S. Dist. Miss.

Charged 3-18-76 by grand jury: when shipped, crabmeat contained *E. coli* and other bacterial filth, and the crabmeat had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Nolo contendere plea by corporation; fine. Guilty

plea by president; fine and probation. (F.D.C. No. 60264; S. No. 39-818 H et al.; N.J. No. 44)

Pioneer Food Stores Cooperative, Inc., Carlstadt, Dist. N.J.

Charged on or about 10-8-75: enriched rice, beans, flour, two lots of spring water in plastic jugs, and dog food were exposed to contamination by rodents, were held under insanitary conditions, and were rodent gnawed; a noodle mix was exposed to contamination by insects, was held under insanitary conditions, and contained insects; and rice, breakfast cereals, walnuts, spaghetti, beans, black-eyed peas, raisins, grits, and salt were exposed to contamination by rodents and were held under insanitary conditions; 402(a)(3), 402(a)(4). Guilty plea; fine. (F.D.C. No. 60268; S. No. 10-341 H et al.; N.J. No. 45)

Wing Sing Chong Co., Inc., and Steve Siu, treasurer, San Francisco, N. Dist. Calif.

Charged 4-3-75: rice, tapioca flour, and bean thread were held in a building accessible to rodents and were exposed to rodent contamination; and the rice contained rodent filth; 402(a)(3), 402(a)(4). Guilty plea by corporation; fine. Nolo contendere plea by individual; fine. (F.D.C. No. 60007; S. No. 94-041 G et al.; N.J. No. 46)

NOTICES OF JUDGMENT on Injunction Actions

Amend Drug & Chemical Co., Inc. Ruger Chemical Co., Inc., and Hyman Levine, president, **Philip Salzman**, vice president, and **Bernard Grobman**, secretary & treasurer, Irvington, Dist. N.J.

Charged 3-25-75 in complaint for injunction: that the defendants manufactured, processed, packed, labeled, distributed interstate, and held for sale after interstate shipment of the drug components, various drugs for human use; that FDA inspections of the defendants' Irvington plant disclosed a number of specified inadequacies; that the circumstances used for the manufacture, processing, packing, and holding of such drugs failed to conform with current good manufacturing practice; that for some drugs, their strength differed from or their quality and purity fell below the standards of the official compendia; that the labeling of some such drugs contained false and misleading statements with respect to the identity, strength, quality, and purity of the drugs; that the defendants were well aware that their activities were in violation of the law; and that defendants' violations presented an extreme danger to public health since the defendants repackaged hazardous industrial chemicals (as well as drugs) in the same area and dealt in bulk drugs, many of which were similar in appearance; 501(a)(2)(B), 501(b), 502(a). A consent decree of permanent injunction enjoined the interstate shipment of drugs from the defendants' plant and the production of drugs at the plant from interstate ingredients, unless and until: a number of specified conditions of current good manufacturing practice were met; all the drugs produced by the defendants which were on hand or in channels of distribution were examined by the defendants; necessary tests and recalls were made; all such drugs were destroyed or brought into compliance with the law; all consignees of bulk drugs that had no analysis performed were so informed; and, after compliance with the above terms, the defendants were enjoined from the violations of the law specified in the complaint. (Inj. No. 694; S. No. 55-857 H et al.; N.J. No. 47)

C.E.B. Products, Inc. (formerly Dark Eyes, Inc.), Charlotte E. Barth, president, and **Herman Goldenberg**, vice president, Chicago, N. Dist. Ill.

Charged 5-30-74: that the defendants caused the manufacture of Long Nails methyl methacrylate fingernail lengthener kits; that the defendants supervised the manufacture of such article in part from methyl methacrylate which had been shipped in interstate commerce, labeled the finished products, and distributed the kits in interstate and intrastate commerce; that the kits consisted in part of methyl methacrylate in its monomer form, which was well known as a sensitizer, which, when applied to the fingernails as directed, would penetrate and cause skin reactions, which had the potential of forming an impermeable coating over the fingernail interfering with respiration of sensitive underlying tissues, and which was a poisonous and deleterious substance that might render the article injurious to users, when used as directed or as ordinarily used; and that the defendants were well aware that their activities were in violation



of the law; 601(a).

The defendants denied the charges; and the court denied the Government's motion for a temporary restraining order. The parties served written interrogatories on each other. Subsequently, the court issued a preliminary injunction enjoining the defendants from the violations complained of, but not ordering the defendants to recall the kits. The court said in its opinion:

"The Government's prayer for relief also requested that the court order defendants to notify all persons, down to the retail level, to whom any of the cosmetic had been distributed, that the product contained a poisonous or deleterious substance and to 'direct all such persons to return the article to the defendants.' All parties, and the court, have viewed that paragraph as a demand for a judicially-ordered 'recall' of those packages of Long Nails which may still be sitting on store or warehouse shelves. Defendants strenuously object to this demand, arguing that the court is without authority under the Federal Food, Drug and Cosmetic Act (hereinafter cited as 'the Act' or 'the FDCA') to order a recall, and that even if such authority exists, the court should decline to enter such an order as a matter of discretion. In light of the apparent novelty and the undoubted seriousness of this question, the court ordered briefs on the point and took the issue under advisement. After reviewing the memoranda of both parties, the court ruled orally from the bench that it had concluded that it possessed no power in the circumstances of this case to order a recall. This Memorandum Opinion is intended to set forth the reasons behind that conclusion.

"The Government brought this suit for injunction pursuant to section 302(a) of the Act. . . . The section appears to contemplate only negative injunctions prohibiting statutory violations, rather than any sort of mandatory or affirmative relief. . . . Indeed, one close student of the Act has concluded that '[a]n injunction [under the FDCA] should forbid only the acts which are prohibited by the statute.' Toulmin, *The Law of Foods, Drugs and Cosmetics* § 7.4, at 100 (1963). Thus, no explicit statutory authorization for either administrative or judicial recalls exists. . . .

"The legislative history of the Act apparently contains no reference to the recall remedy. Indeed, the legislative background is of relatively minimal assistance in determining congressional intent with respect to the injunctive provision at all; section 302 caused little discussion. . . .

"Initially, it is noteworthy that the Federal Food and Drugs Act of 1906 contained no injunctive provision. The basic judicial and administrative procedures for enforcement of the 1906 Act's prohibitions were four-fold: (1) criminal proceedings, (2) libel for condemnation proceedings, and (3) administrative exclusion of imports, and (4) administrative inspection proceedings concerning seafood. . . . Thus, there existed no injunctive precedent which Congress could be deemed to have approved in section 302(a) or which could have guided Congress in shaping that provision.

"Secondly, the scant legislative history which does exist suggests, if anything, that Congress was concerned with the harshness of the remedies upon manufacturers. . . . Given this orientation, and the potential difficulties concomitant to a recall, . . . it is difficult to conclude that Congress intended section 302(a) to authorize judicial recalls.

"Despite this congressional silence, recalls have played an increasingly significant role in the FDA's enforcement of the Act. Approximately 18 years ago, the agency initiated procedures for the voluntary recall of violative products, as an alternative to seizures, prosecution, and injunctive actions. . . . In March 1971, a subcommittee of the House of Representatives Committee on Government Operations held a hearing on these recall practices. . . . Questioning of senior FDA officials made clear that neither the members of the subcommittee nor the FDA considered the Act to authorize judicial or administrative recalls. . . .

"The report growing out of this investigation concluded that 'no statutory authorization for recalls exists,' . . . and that the 'FDA cannot legally enforce its requests or demands for recall action.' . . .

"The government contends that these materials address only the issue of administratively-ordered recalls. Granting that the

congressional investigation may have been limited to that topic, the court cannot overlook the reference to judicial recalls in the colloquy between Representative Goldhammer and Mr. Grant. Furthermore, if any of the members of the subcommittee or any of those testifying on behalf of the FDA were of the opinion that statutory authority for judicial recalls existed, it is surprising that this view was not expressed at some point during the hearing or in the report.

"Only two cases have been discovered in the official reporters wherein recall was judicially sanctioned in litigation arising under section 302(a). In neither instance, however, did the court address the question at issue here. In *United States v. Lanpar Co.*, 293 F.Supp. 147 (N.D. Texas 1968), the court merely entered findings of fact and conclusions of law and ordered the defendant drug company to recall and destroy certain reports, bulletins, and leaflets, and drugs containing combinations of digitalis and thyroid. . . . The second case, *United States v. Lit Drug Co.*, 333 F.Supp. 990 (D.N.J. 1971), had been preceded by a history of 15 voluntary recalls of adulterated drugs by defendants. . . . Significantly, the court expressly noted that '[d]efendants do not quarrel with the government demand for a recall of drugs. . . .'

"In a somewhat analogous case to this one, *United States v. Parkinson*, 135 F.Supp. 208 (S.D.Cal. 1955), *aff'd*, 240 F.2d 918 (9th Cir. 1956), heavily relied upon by defendants, the court determined that it lacked authority under section 302(a) to order the manufacturer of an adulterated product to make restitution to the purchasers of the product. Both parties seem to agree that 'restitution' and 'recall' are different labels for essentially the same result. . . . In conclusion, the court [in *United States v. Parkinson*] noted that restitution, in stark contrast to the traditional preventive character of injunctive relief, was essentially punitive in nature and found nothing in the legislative history of the FDCA to support any sanction other than criminal prosecution, seizure, and traditional negative injunctions. . . .

"Here, the government questions the continuing validity of *Parkinson* in light of the well-accepted proposition that a federal court, unless restricted by statute, may exercise the full range of equitable powers in support of its jurisdiction and in order to do complete justice in a particular case. Accordingly, plaintiff argues that, for this court 'to do justice completely, and not by halves,' . . . a recall must be ordered. * * *

"It is clear that the FDCA establishes a specific, three-fold enforcement scheme of injunctions, seizure, and criminal prosecutions. This system provides adequate before and after the fact remedies. Injunctive suits are appropriate for preventive relief, and criminal and seizure proceedings are available after the allegedly offending article has begun movement in interstate commerce. In seeking this recall, the government is asking for judicial sanction of an additional arrow for its already well-equipped bow. Although the institution of multiple seizure actions may be more burdensome than a single recall to the government, that alternative remains as a valid and frequently-used enforcement tool. Moreover, after studying the FDA's voluntary recall program, the aforementioned House subcommittee indicated its view on the efficiency of seizure by its statement that 'the statute appears to provide adequate authority to clear the market of potentially dangerous or fraudulent products by seizure alone . . . ' (emphasis added).

"No Hobson's choice . . . is involved in the FDCA procedures. Congress may have considered the probability that the adulterated nature of a cosmetic may not become known until after its distribution in interstate commerce and its use by consumers, as appears to have been the case with 'Long Nails'. Furthermore, where the public danger is clear, the literature indicates that manufacturers are willing to institute their own recalls or to cooperate with the FDA in a recall effort. . . .

"Thus, this court cannot conclude that 'effective enforcement [of the Act] could . . . only be expected,' . . . by interpreting section 302(a) or the statute in general and the circumstances surrounding its enactment, to allow the court to exercise its equitable powers to order a recall of adulterated products already on the market. This court is convinced that such an interpretation would constitute an unjustifiable judicial amendment of the FDCA. A review of the legislative history and



statutory scheme can only lead to the conclusion that it was not the congressional purpose in the FDCA to empower courts to issue injunctions beyond prohibiting the violations specifically referred to therein.

"However, even assuming that the statutory language and policy and the legislative history supported a judicially-ordered recall under section 302(a) or inherent equitable jurisdiction, this court, in the exercise of its equitable discretion, would decline to enter such an order. A balancing of the parties' interests, plus due regard for the public welfare, does not support recall relief.

"Although two hearings have been held in this matter, the case is still in a preliminary stage. A full trial on the merits remains for the future. With the case in this posture, a mandatory injunction should be issued only in exceptional circumstances. . . .

"Defendants have presented evidence to cast serious doubt upon the wisdom of ordering a recall. The uncontroverted testimony of the president of defendant C.E.B. Products, Inc., established that a recall would render the company insolvent and necessitate bankruptcy proceedings. Although it is highly doubtful whether any business has a constitutional right to remain in business, . . . especially where it is found to be illegal, . . . courts are properly reluctant to issue orders at the preliminary stage of litigation where the effect may be to eliminate the party as a competitive economic unit. . . . As Congressman Fountain remarked during the 1971 hearing, '[w]e are interested in protecting the consuming public but we are likewise interested in manufacturers—they have to survive.' . . .

"If a recall were ordered and if C.E.B. Products were to survive until a final hearing, defendants' costs of reimbursing distributors and of storage, and other hardships, might render an ultimate determination in their favor a somewhat pyrrhic victory.

"The injuries suffered by consumers, upon which proof was presented—nails splitting and falling off, redness, soreness, nail disfigurement, and infection—albeit serious and uncomfortable, are not of that severity and proportion to warrant the extraordinary remedy sought by the Government. It appears in most cases that the harm can be treated.

"Thus, even assuming that recall is an available alternative remedy, a careful consideration of the public and private interests in this case dictates that a recall not be ordered."

Meanwhile, the defendants moved to enjoin the Government from initiating any more seizure actions against Long Nails pending a hearing on the merits of the Government's complaint for injunction. The Government opposed the granting of such an order. Subsequently the court clarified its order of preliminary injunction against the producers of the product so as to permit exports which were in compliance with the export provisions of the law.

The Government appealed the court's refusal to modify the preliminary injunction to include a recall of the product, the defendant filed a cross-appeal. However, upon stipulation of the parties, the appeals were dismissed, and the defendants undertook a recall of the product. The defendants also entered into a consent decree of permanent injunction which permanently enjoined the complained of violations, and enjoined the labeling, promotion advertising, or, in any manner, the holding for sale of Long Nails kits or any other cosmetic containing methyl methacrylate monomer, and which injunction provided a second recall notification to the persons who had not previously responded and also provided for the destruction of all Long Nails kits on hand or subsequently returned, except those kits in compliance with the export provision of the law. (Inj. No. 669; N.J. No. 48)

NOTICES OF JUDGMENT on Miscellaneous Actions

Methadone and its administration and dispensing for analgesia for only hospitalized patients and outpatients. Cicero, N. Dist. Ill. Charged 4-30-73 by Vito Cancialosi, Cicero, Ill., on behalf of himself and all others similarly afflicted with severe pain, against HEW Secretary Caspar W. Weinberger, FDA Commissioner Charles C. Edwards, and Bureau of Drugs Director Henry E. Simmons in a suit for injunction and declaratory judgment:

that under the defendants' regulations, methadone was only for detoxification or temporary treatment of hospitalized patients, or for analgesia in severe pain for hospitalized patients and outpatients; that the defendants limited its use to hospital pharmacies that had filled out and returned an HEW form; that the plaintiff was discriminated against and disadvantaged as to treatment, because of the arbitrary restrictions on the dispensing of the medication; that the efficacy of the medication was unquestioned; that the defendants discriminated against all nonhospital pharmacies by arbitrarily using only hospital pharmacies; that many severe pain patients were not able to travel to a hospital which had an outpatient pharmacy and which had filled out and returned the HEW form; that, by such conduct, the defendants violated the plaintiff's rights and the rights of the severe pain patients which he represented; that plaintiff sought that the Government be enjoined from limiting the plaintiff's rights to proper medication and from limiting his obtaining methadone only from hospital pharmacies; and that plaintiff sought judgment that severe pain patients should have the right to obtain his medication without obstruction by HEW.

The Government moved to dismiss the action. The court dismissed the action on the grounds that the complaint did not state a claim upon which the court could act so far as jurisdiction was concerned. (Misc. No. 230; N.J. No. 49)

Genisis conjugated estrogens tablets and New Drug Application required for such tablets, Washington, Dist. Columbia.

Charged 7-1-75 by Organon, Inc., West Orange, N.J., against FDA Commissioner Alexander M. Schmidt, and the Federal Food and Drug Administration, in suit for mandamus: that FDA published a *Federal Register* notice about conjugated estrogens tablets describing labeling requirements and inviting abbreviated New Drug Applications from persons not holding approved or effective New Drug Applications; that the plaintiff submitted an abbreviated New Drug Application; that, after 2½ years' correspondence, FDA, contrary to its prior handling, stated that because Organon's product was synthetic (instead of being derived from natural sources) an abbreviated New Drug Application was inappropriate; that plaintiff requested that its application be filed over protest; that more than the statutory 60 days passed and neither had the abbreviated New Drug Application been approved, nor had a written notice of opportunity for hearing been given to the plaintiff; that plaintiff was frustrated in pursuit of its business interests, had no remedy at law, was irreparably damaged and was denied due process by FDA's inaction.

Various extensions of time for the Government to answer were agreed to, in order that FDA might conduct additional analyses of Genisis tablets in order to resolve problems concerning stability of the products. Ultimately, the analyses were completed, FDA advised that the abbreviated New Drug Application would be approved, and the action became moot. Accordingly, the action was dismissed. (Misc. No. 297; N.J. No. 50)

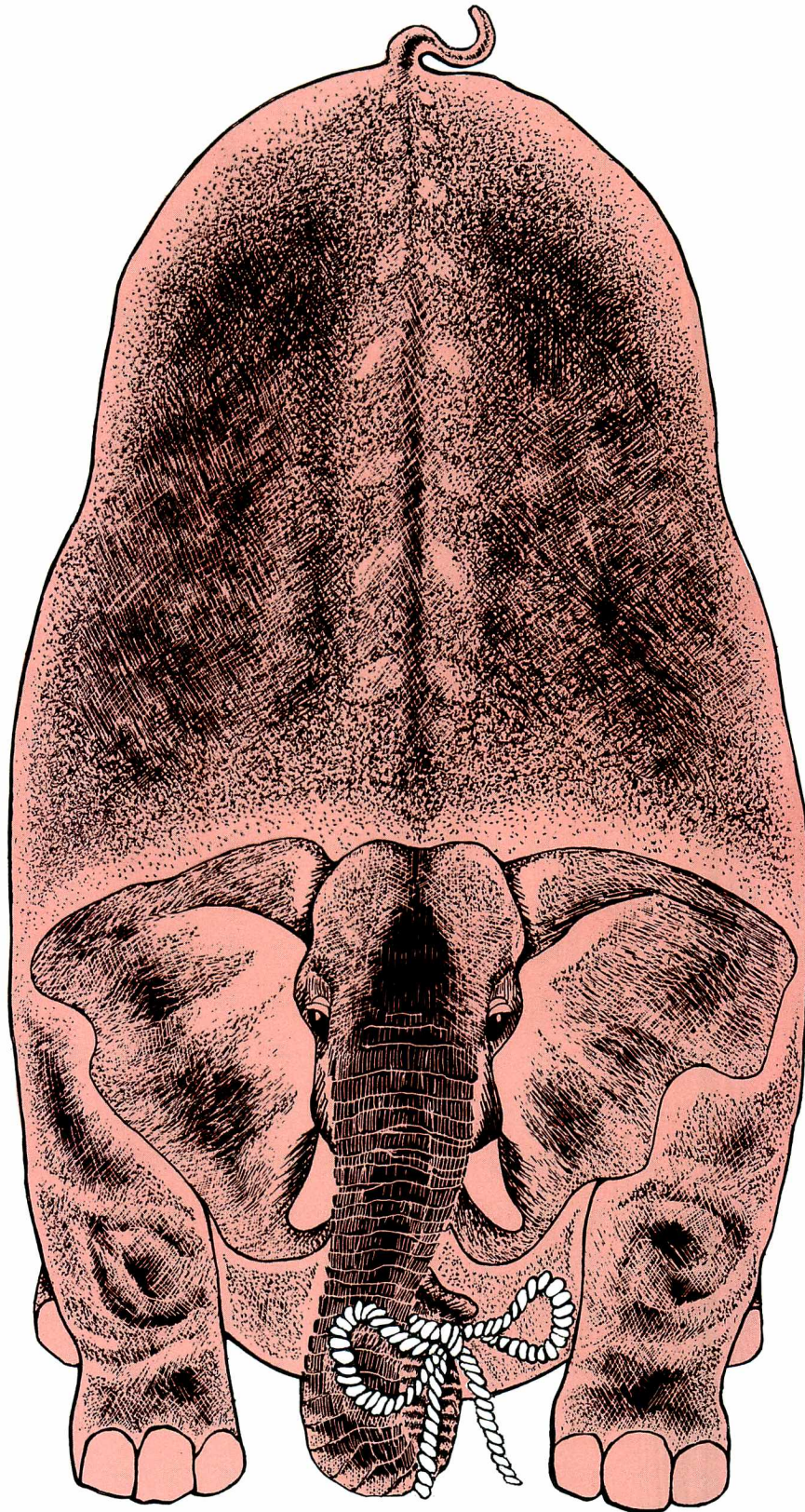
Notices of Judgment are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Notices of Judgment report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against *goods* alleged to be in violation, and criminal and injunction proceedings are against *firms* or *individuals* charged to be responsible for violations. The cases generally involve foods, drugs, devices, or cosmetics which were alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce.

Notices of Judgment are prepared by Food and Drug Division, Office of the General Counsel, DHEW.

Published by direction of the Secretary of Health, Education, and Welfare.

Alexander M. Schmidt, M.D., *Commissioner of Food and Drugs*
Washington, D.C., September 1, 1976

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